AGRICULTURE, RURAL DEVELOPMENT, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2005

THURSDAY, APRIL 1, 2004

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 1:08 p.m., in room SD–192, Dirksen Senate Office Building, Hon. Robert F. Bennett (chairman) presiding.

Present: Senators Bennett, Burns, and Kohl.

DEPARTMENT OF AGRICULTURE

STATEMENTS OF:

ERIC M. BOST, UNDER SECRETARY, FOR FOOD NUTRITION AND CONSUMER SERVICES

WILLIAM T. HAWKS, UNDER SECRETARY FOR MARKETING AND REGULATORY PROGRAMS

ELSA A. MURANO, UNDER SECRETARY FOR FOOD SAFETY

OPENING STATEMENT OF SENATOR ROBERT F. BENNETT

Senator BENNETT. The subcommittee will come to order.

And may I begin by thanking everyone for your willingness to rearrange your schedule and come at this slightly early hour and apologize for being a little late. Senator Byrd cast his 17,000th vote today on the floor and we lingered to pay tribute to him and give him our congratulations.

This is the second hearing to review the fiscal year 2005 budget request. We had Secretary Veneman here last week and we appreciate how responsive she was on the various topics we covered. This week we have several of the Under Secretaries at USDA, as well as the Acting Commissioner of the Food and Drug Administration.

So we look forward to hearing your testimonies. I am going to try to keep this fairly quick because I do have an unavoidable conflict at 2 o'clock and I would like to be through before then if we can. If we cannot, we can go over that time but I will be unable to participate in that.

So I have no other further opening statement, other than to say welcome to all of you. Thank you for your service to the United States of America, your willingness to interrupt other careers to render public service.

This is the last time in this administration we will have the opportunity to offer our thanks for what you do. And it goes unappreciated and unnoticed too much. So I would like to be sure on this occasion to do that.

Senator Kohl.

Senator KOHL. I thank you, Mr. Chairman, and we welcome Mr. Bost, Dr. Murano, Mr. Hawks and Dr. Crawford.

For the sake of time, Mr. Chairman, I will forego my opening statement but look forward to testimony and to ask questions.

Thank you, Mr. Chairman.

PREPARED STATEMENT OF SENATOR DURBIN

Senator BENNETT. The subcommittee has received a statement from Senator Durbin which we will insert into the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR RICHARD J. DURBIN

Chairman Bennett, thank you for holding this important hearing today. I look forward to working with you and my Subcommittee colleagues on the fiscal year 2005 (fiscal year 2005) Agriculture budget. Mr. Chairman, I would like to welcome our witnesses Eric Boast, Under Secretary for Food, Nutrition, Consumer Services, Elsa Murano, Under Secretary for Food Safety, William Hawks, Under Secretary for Marketing and Regulatory Programs and Lester Crawford, Acting Commissioner for Food and Drug Administration.

I'd like to take a few minutes this morning to talk about some very important issues under USDA's jurisdiction.

An issue of great importance to me is dietary supplements. Obviously, I was pleased about the ban on ephedra and Dr. McClellan's commitment to look at citrus autantium, aristolochic acid and usnic acid: all supplement ingredients I believe are dangerous. I was also pleased to see FDA take action against anabolic steroids.

I want to see progress toward protecting the public from dangerous supplements continue. However, I believe several critical changes need to be made to the Dietary Supplement Safety and Education Act to make your job easier. First, I believe we need to require that supplement manufacturers report to the FDA when serious adverse events occur. I'm not talking about someone getting a little dizzy from taking a supplement. I'm talking about death, incapacity and hospitalization.

It is absolutely necessary that we know when a product is harming people. The Office of the Inspector General at HHS estimates that the FDA receives reports of less than 1 percent of all adverse event associated with dietary supplements. How can the FDA effectively protect the public if it doesn't know when a product is causing harm?

The Institute of Medicine's report that came out today supports a mandatory system of adverse event reporting. It says, "while spontaneous adverse event reports have recognized limitations, they have considerable strength as potential warning signals of problems requiring attention, making monitoring by the FDA worthwhile".

The second change I would like to see made to DSHEA is a requirement to premarket safety review of supplements containing stimulants. I don't believe that every natural substance needs to be subject to pre-market safety testing, but at the very least, DSHEA should be changed so stimulants are tested before marketed. When a supplement raises people's blood pressure, increases their metabolism and constricts their blood vessels, it is only prudent that we test the product before it is marketed.

Another issue of importance deals with childhood obesity. Under Secretary Bost, I know that you've been working with my staff to develop a school-based demonstration project in Illinois to help students make better food choices while they are at school.

I've been in school cafeterias. I've watched students pass by the fresh vegetables and go straight for the fries. I've also seen them put fruit on the tray and then dump the tray after lunch, fruit untouched. We have to do a better job of helping our young people understand nutrition and why it matters.

I want to commend you and your staff for your efforts to work with us to develop some innovative demonstration projects in Illinois schools to help students make better food choices.

Chairman Bennett and Senator Kohl, thank you again for the opportunity to talk about these issues and the fiscal year 2005 Budget.

Senator BENNETT. Thank you very much. Let us go in the following order: Mr. Bost, who is the Under Secretary for Food, Nutrition, and Consumer Services of the USDA; William Hawks who is the Under Secretary for Marketing and Regulatory Programs; Elsa Murano, who is the Under Secretary for Food Safety. And then, with the USDA having been heard from, we will turn to the Acting Commissioner of the FDA, Dr. Lester Crawford.

Mr. Bost.

STATEMENT OF ERIC M. BOST

Mr. BOST. Good afternoon and thank you very much, Mr. Chairman. Good afternoon, Senator Kohl.

Thank you for this opportunity to present the Administration's budget request for fiscal year 2005 for the Food, Nutrition, and Consumer Services.

You have my written testimony so I will try to be brief.

Since I have been Under Secretary, I have focused my attention and energy on these priority challenges facing the nutrition assistance programs: expanding access to programs so that all eligible persons may participate; addressing the epidemic of obesity that threatens the health of individual Americans, our economy and health care system; and improving the integrity with which our programs are administered at all levels.

Let me just briefly review some of our accomplishments over the course of the last 3 years. We have reached substantially more participants in each of our major programs, 5.8 million more people in Food Stamps; 1.6 million more children receiving a free or reduced priced lunch; over 1.4 million more children receiving a school breakfast; and over 400,000 more women, infants and children participate in the WIC program each month since January of 2001.

We have successfully implemented the provisions of the 2002 Farm Bill that met the Administration's goals, including the important steps of restoring Food Stamp benefits to legal immigrants and increasing flexibility for the States.

We have also expanded the Electronic Benefits Transfer, EBT, to all 50 States, the District of Columbia, Puerto Rico and the Virgin Islands. EBT now delivers over 95 percent of all food stamp benefits. At some point in time we are going to have to change the name because there will no longer be any food stamps.

We reduced food stamp payment errors for the 4th year in a row, the lowest that it has ever been in the history of the Food Stamp Program, at 8.26. We also reduced food stamp trafficking to less than 2.5 cents for each benefit dollar issued, down by a third since 1996–1998.

We also promoted healthy lifestyles as a top priority through the President's HealthierUS initiative, working with public and private partners to promote healthy eating and physical activity and to foster a healthy school nutrition environment.

We promoted a healthy way for children and adults across the program to increase emphasis on nutrition education. We are currently working in concert with the Department of Health and Human Services to update the Dietary Guidelines and a revision of the Food Guide Pyramid.

We achieved a clean financial statement for FNS for the fifth consecutive year in support of the President's initiative to improve financial management across the Government.

I am very proud of these accomplishments, however much more work remains to be done.

In terms of supporting the goals of the President's budget, the President's budget for fiscal year 2005 requests $50.1 billion in new budget authority.

FOOD STAMP PROGRAM

Food Stamps, at $33.6 billion would serve an average of 24.9 million people each month. The Administration's budget continues the $3 billion reserve appropriated in fiscal year 2004.

CHILD NUTRITION PROGRAM

In terms of the Child Nutrition Programs, the request of $11.4 billion supports an increase in school lunch participation from 28 million children to over 29 million children. It also supports an increase in school breakfast participation of over 1 million children from 8 million to 9 million children.

WIC PROGRAM

In our WIC Program, the President's budget proposes $4.8 billion for WIC Program to provide food nutrition, education and a linkage to health care to a record level monthly average of 7.86 million needy women and young children. I think this speaks clearly to the President's commitment to this program. Additionally, the $125 million contingency reserve fund is available if there is a need for a increase if participation or food cost exceeds our projection.

One of the things that I believe is very important that we are spending a great deal of time on, not only in my area but across the country, is addressing the overweight and obesity. Poor dietary choices and sedentary lifestyles are having a serious impact on the health and well being of this entire country.

The most recent figures indicate that 62 percent of all adults in this country are overweight. Estimated health care costs at $123 billion, and also 400,000 deaths are directly related to us being overweight.

Senator BENNETT. Excuse me. Is that an annual cost of $123 billion?

Mr. BOST. $123 billion, that is correct.

Senator BENNETT. Annually?

Mr. BOST. Annually.

Senator BENNETT. That would pay for a lot of health care.

Mr. BOST. Yes, but we are eating ourselves to death.

$20 million for breast feeding peer counseling, $2.5 million to expand the successful Eat Smart Play Hard campaign so we can integrate the nutrition assistance programs to promote healthy eating

and physical activity. $1.65 million is requested to fund the updated 2005 Dietary Guidelines and the Food Guide Pyramid. We believe this is very important, given the fact that Americans are spending on average $33 billion a year on weight loss products, books and et cetera, to help them lose weight. We are spending that money even though we are getting heavier.

NUTRITION PROGRAMS ADMINISTRATION

In addition, the President's request includes an increase of $7 million in our administrative budget which will be targeted at improving integrity in the Food Stamp Program, improving the accuracy of certifications for free and reduced price school meals and invigorating our oversight, training and technical assistance activities with our State and local partners.

As a part of our Nutrition Programs Administration, we are requesting $152 million, an increase of $14.7 million.

Our total request for Federal administrative resources, including those activities funded directly from the program accounts, represents only 0.39 percent of the program resources for which we are responsible.

PREPARED STATEMENTS

In conclusion, the President's direction has been very clear. The Administration request sets priorities to ensure access, maintain and improve integrity and supports our efforts to address the public health threat of overweight and obesity among all Americans in this country.

Thank you, Mr. Chairman.

[The statements follow:]

PREPARED STATEMENT OF ERIC M. BOST

Thank you Mr. Chairman and members of the subcommittee for this opportunity to present the Administration's budget request for fiscal year 2005 for the Food, Nutrition and Consumer Services (FNCS).

During the past 3 years as Under Secretary for the Food, Nutrition and Consumer Services, I have focused my attention and my energy on three central challenges facing the Federal nutrition assistance programs: expanding access to the programs so that all eligible persons can make informed decisions about whether to participate; addressing the epidemic of obesity that threatens the health of individual Americans, and our economy and health care system collectively; and improving the integrity with which our programs are administered, at all levels, so that we are the best possible stewards of the public resources with which we are entrusted.

Let me first review briefly some key accomplishments achieved over the last 3 years:

—We are reaching substantially more participants in each of our major programs: 5.8 million more people in food stamps, 1.6 million more children receiving a free or reduced price school lunch, over 1.4 million more in school breakfast, and over 400,000 more women, infants and children each month in WIC since January 2001.

—We successfully implemented the provisions of the 2002 Farm Bill that met the Administration's goals of simplifying policies, improving access, and ensuring program integrity, including the important steps of restoring benefits to legal immigrants and increasing flexibility for the States.

—We expanded electronic benefits transfer (EBT) to all 50 States, the District of Columbia, Puerto Rico, and the Virgin Islands; EBT now delivers over 95 percent of all food stamp benefits.

—We have seen food stamp payment errors fall for the 4th year in a row, reaching the lowest level ever—8.26 percent—in 2002.

—We have reduced food stamp trafficking to less than 2.5 cents of each benefit dollar issued, down by one-third since 1996–1998.
—We have made healthy lifestyles a top priority through the President's HealthierUS initiative. We are working with public and private partners, such as the National 5 to 9 a Day Partnership, to increase fruit and vegetable consumption and have developed a soon to be released kit for schools entitled "Fruits and Vegetables Galore: Helping Kids Eat More." We are also expanding school-based efforts to promote healthy eating, and to foster a healthy school nutrition environment through technical assistance, training and nutrition education materials that help schools assess and improve the school nutrition environment, including improvements in school meals and overall food policies.
—We have focused on promoting healthy weight for children and adults across programs through the Eat Smart. Play Hard.™ campaign, and within programs through Team Nutrition, the Fit WIC obesity prevention projects, and efforts to improve Food Stamp Program nutrition education.
—We are working in concert with the Department of Health and Human Services to update the Dietary Guidelines for Americans, and we are revising the Food Guide Pyramid to ensure that each reflects the most comprehensive, up-to-date science available in order to provide clear and useful nutrition information to American consumers.
—We achieved a clean financial statement for FNS for the 5th consecutive year, in support of the President's management agenda initiative to improve financial management across government.

I am proud of these accomplishments, and the hard work that they represent from USDA staff, from the Congress, and from our State and local program partners. But much important work remains to be done. I'd like now to review the budget request and the improvements in performance and results that it is designed to support.

The President's budget for fiscal year 2005 requests $50.1 billion in budget authority to continue this critical work. This record request reflects the Administration's long-standing commitment to protect our children and low-income households from hunger and the health risks associated with poor nutrition and physical inactivity through the Nation's nutrition safety net. The purposes to which we will put this substantial public commitment are clear: first, we seek to improve the public's awareness of our programs and ease of access for all eligible persons, and second, through both the Federal nutrition assistance programs and the Center for Nutrition Policy and Promotion (CNPP), we will continue to do our part to address the growing public health threat that overweight and obesity poses to all Americans. Finally, we will strive to enhance the efficiency and accuracy with which these programs are delivered.

ENSURING PROGRAM ACCESS

This Administration has demonstrated a long-term commitment to the Federal nutrition assistance programs and to the Americans whom they assist. The most fundamental expression of this commitment is making certain that sufficient resources are provided for these programs so that all who are eligible and in need have ready access to these critical benefits. We have delivered to you a budget that funds anticipated levels of program participation, while acknowledging the inherent difficulties in making such projections.

For the Food Stamp Program, the budget continues the $3 billion contingency reserve appropriated in fiscal year 2004 but also offers, as an alternative, a proposal for indefinite budget authority for program benefits. This authority would be an efficient way to ensure that benefits are funded even as economic circumstances change, a goal we all share. In WIC, the $125 million contingency reserve appropriated in fiscal year 2003 continues to be available to the program should participation or food costs exceed the levels anticipated in the budget. Should this not be sufficient, we are committed to working with you to ensure that WIC is properly funded.

Adequate program funding, however, is not enough to ensure access to program services for those who need them. Program structure and delivery methods must be designed so as not to create the types of barriers to program participation that can result in their underutilization. As we move forward with the reauthorization of the Child Nutrition and WIC Programs, improving program delivery and ensuring the access of eligible people who wish to participate will remain fundamental principles.

ADDRESSING OVERWEIGHT AND OBESITY

Poor dietary choices and sedentary lifestyles are having a serious impact on the health and well being of all Americans. Obesity and overweight are widely recog-

nized as a public health crisis. The costs of these conditions are enormous—reduced productivity and increased health care costs estimated at over $123 billion, and, most sadly, unnecessarily premature deaths for over 300,000 Americans annually. The Federal nutrition assistance programs can play a critical role in combating this epidemic by promoting better diets through nutrition education and promotion. These program services, along with the work of the Center for Nutrition Policy and Promotion, are an integral part of the President's HealthierUS initiative, and the budget reflects our continuing commitment to this effort. It includes $5 million for ongoing demonstration projects to explore new ways for the WIC program to reduce and prevent unhealthy weight among our children. We are also seeking $2.5 million to expand our very successful Eat Smart. Play Hard.™ campaign, and to develop an integrated, family-oriented approach to nutrition education that cuts across all of the Federal nutrition programs and complements efforts in schools and other program settings to encourage healthy eating and physical activity.

Our request also supports FNCS' CNPP, which works with the Department of Health and Human Services and other agencies to promote good nutrition across all segments of the population. The budget includes resources that are critical to the development and promotion for the updated 2005 Dietary Guidelines for Americans and the concurrently revised food guide system, providing essential tools to communicate the Guidelines in ways that motivate Americans to improve their eating and physical activity behaviors. The requested funding for CNPP will enable us to capitalize on the investments we have already made with a new opportunity to build upon public awareness of basic nutrition messages with an enhanced food guide system that will target individual needs.

ENHANCING PROGRAM INTEGRITY AND DELIVERY

With this budget request, we are asking the Nation to entrust us with over $50 billion of public resources. We are keenly aware of the immense responsibility this represents. To maintain the public trust, we must demonstrate our ongoing commitment to be good stewards of the resources we manage, as an essential part of our mission to help the vulnerable people these programs are intended to serve.

This is not a new commitment. As I noted earlier, in fiscal year 2002, the most recent year for which data is available, the Food Stamp Program achieved a record high payment accuracy rate of 91.74 percent. We have also been working to develop strategies to improve the accuracy of eligibility determinations in our school meals programs—an issue of mutual concern to all those that care about these programs. The budget features dollar and staff year resources which will allow us to continue to work closely with our State and local partners on both of these essential integrity initiatives—continuing both our successes in the Food Stamp Program and our intensified efforts in school meals.

In the WIC program, we are requesting $20 million to continue our initiative to assist States with the modernization of their information technology infrastructure. These systems are essential underpinnings for the improvements in program management, program integrity, and, most importantly, program delivery that need to be achieved. The Administration has worked closely with the Office of Management and Budget (OMB) and the WIC community to fashion a procurement strategy that will ultimately produce a series of core model WIC systems. States updating their WIC systems will be able to select from among these model core systems as starting points for their own implementation, thus reducing their costs.

In the remainder of my remarks, I'd like to touch on several key issues:

FOOD STAMP PROGRAM

The President's budget anticipates serving a monthly average of 24.9 million persons in fiscal year 2005, an increase of 1.2 million over our projections of the current fiscal year. Our $33.6 billion request supports this level of service. In addition, the budget continues the $3 billion contingency reserve appropriated in fiscal year 2004. While the President's budget anticipates continuing improvement in the Nation's economy, Food Stamp Program participation traditionally continues to rise for some time after the aggregate employment begins to improve. Moreover, we have made a concerted effort over the last 3 years to raise awareness of the benefits of program participation and encourage those who are eligible, especially working families, senior citizens, and legal immigrants, to apply. The rate of participation among those eligible to participate increased 2 years in a row, after 5 years of declines, reaching 62 percent in September 2001. However, many eligibles remain who could be participating but are not. We have been aggressive in promoting the message that the Food Stamp Program Makes America Stronger in the sense that the program puts healthy food on the tables of low-income families and has a positive impact on local

economies. We have just recently embarked on a media campaign to carry this message and to reach those who are eligible but not participating. We have also paid particular attention to those legal immigrants who have had their eligibility restored by the Farm Bill by carrying messages on Hispanic radio stations across the country.

These factors make this a particularly challenging period to forecast program participation and costs. To ensure the adequacy of resources available to the program, and as an alternative to the traditional contingency reserve, we have proposed indefinite authority for program benefits and payments to States and other non-Federal entities.

CHILD NUTRITION PROGRAMS

The President's budget requests $11.4 billion to support the service of appealing, nutritious meals to children in public and private schools and child care facilities through the Child Nutrition Programs in fiscal year 2005. In the National School Lunch Program, we anticipate serving over 29 million children per day in fiscal year 2005. Similarly, the School Breakfast Program will serve approximately 9 million children each school day. The request for budget authority is a slight decrease from levels appropriated in fiscal year 2004. This is because the rate of program growth in fiscal year 2004, to date, has been slightly less than anticipated. As a result, the anticipated carry-over resources, in conjunction with the budget request, will fully fund the projected level of program activity.

Several components of the Child Nutrition Programs expire at the end of March. We urge the Congress to move quickly to extend these provisions before they expire to ensure that all aspects of the Child Nutrition Programs continue to operate without interruption. We also want to work with the Congress to reauthorize and improve the entire range of Child Nutrition Programs, consistent with the principles outlined last year. These principles include ensuring that all eligible children have access to program benefits as well as streamlining the administration of programs to minimize burdens, supporting healthy school environments and strengthening program integrity.

Reauthorization provides an opportunity to address our continuing concern that the certifications of children to receive free and reduced price meals are not performed as accurately as they reasonably could be. Correct certifications are a priority to ensure that school meal funds go to those most in need, and the many other Federal, State, and local resources that use this same data are properly targeted as well.

In sum, we are committed to working with Congress to reauthorize the Child Nutrition Programs and to reinvesting any savings achieved in the process back into these important programs for program improvements.

WIC

In fiscal year 2005, the President's budget request of $4.79 billion anticipates providing essential support to a monthly average of 7.86 million women, infants and children through the Special Supplemental Nutrition Program for Women, Infants and Children (WIC). This is an increase of 60,000 participants per month from anticipated fiscal year 2004 participation levels. Additionally, the $125 million contingency reserve, appropriated in fiscal year 2003, remains available to the program should participation or food costs exceed our projections. The Administration remains steadfast in its support of WIC and is committed to working with Congress to ensure its proper funding. Finally, the request includes $20 million to continue our peer counseling initiative that is designed to enhance both rates of initiation and duration of breastfeeding among WIC participants.

THE EMERGENCY FOOD ASSISTANCE PROGRAM (TEFAP)

Through TEFAP, USDA plays a critical supporting role for the Nation's food banks. This support takes the form of both commodities for distribution and administrative funding for States' commodity storage and distribution costs. Much of this funding flows from the States to the faith-based organizations that are a cornerstone of the food bank community. The President's budget requests the fully authorized level of $140 million to support the purchase of commodities for TEFAP. Additional food resources become available through the donation of surplus commodities from USDA's market support activities. In recent years, these donations have increased the total Federal commodity support provided to the Nation's food banks by almost 300 percent. State administrative costs, a critical form of support to the food bank community, are funded at $50 million in the President's request.

NUTRITION PROGRAMS ADMINISTRATION

We are requesting $152 million in our Nutrition Programs Administration account, which reflects an increase of $14.7 million in our administrative funding. This increase supports the Child Nutrition and Food Stamp Programs integrity activities mentioned earlier, as well as a number of nutrition guidance initiatives under the Center for Nutrition Policy and Promotion. These resources are absolutely critical to our ability to successfully execute the mission of the Food, Nutrition and Consumers Services. Our total request for Federal administrative resources, including those activities funded directly from the program accounts, represents only about 0.39 percent of the program resources for which we have stewardship. I believe that we need this modest increase in funding in order to maintain accountability for our $50 billion portfolio and to assist our State and local partners in effectively managing the programs.

Mr. Chairman, I appreciate the opportunity to share my thoughts with you, and would be happy to answer any questions you may have.

PREPARED STATEMENT OF ROBERTO SALAZAR, ADMINISTRATOR, FOOD AND NUTRITION SERVICES

Thank you, Mr. Chairman, and members of the Subcommittee for allowing me this opportunity to present testimony in support of the fiscal year 2005 budget request for the Food and Nutrition Service.

The Food and Nutrition Service is the agency charged with managing the Nation's nutrition safety net and providing Federal leadership in America's ongoing struggle against hunger and poor nutrition. Our stated mission is to increase food security and reduce hunger in partnership with cooperating organizations by providing children and low-income people access to nutritious food and nutrition education in a manner that inspires public confidence and supports American agriculture.

In fiscal year 2005, the President's budget requests a total of $50.1 billion in new budget authority to fulfill this mission through the Federal nutrition assistance programs. With this record request we will touch the lives of more than 1 in 5 Americans over the course of a year. This includes providing nutritious school lunches to an average of 29 million children each school day (NSLP), assisting with the nutrition and health care needs of 7.86 million at risk pregnant and postpartum women (WIC) and children each month, and ensuring access to a nutritious diet each month for 24.9 million people through the Food Stamp Program (FSP). These are just 3 of our 15 Federal nutrition assistance programs, which also include such important programs as the School Breakfast Program (SBP), The Emergency Food Assistance Program (TEFAP), the Summer Food Service Program (SFSP), the Child and Adult Care Food Program (CACFP), the Food Distribution Program on Indian Reservations (FDPIR), and the Commodity Supplemental Food Program (CSFP). Through the range of design and delivery methods these programs represent, FNS seeks to serve the children and low-income households of this Nation and address the diverse ways and circumstances in which hunger and nutrition-related problems present themselves.

The resources we are here to discuss must be viewed as an investment—an investment in the health, self-sufficiency, and productivity of Americans who, from time to time, find themselves at the margins of our prosperous society. Under Secretary Bost, in his testimony, has outlined the three critical challenges which the Food, Nutrition and Consumer Services team has focused on under his leadership: expanding access to the Federal nutrition assistance programs, promoting healthy weight to address the problems of overweight and obesity; and, improving the integrity with which our programs are administered. In addition to these fundamental priorities specific to our mission, President Bush has laid out an aggressive agenda for management improvement across the Federal Government as a whole—the President's Management Agenda. This agenda seeks to protect the taxpayers' investment in all Federal activities by enhancing the accuracy and efficiency of program delivery and reducing improper payments, by improving decision-making through the integration of performance information into the budget process, by building partnerships with faith and community based organizations, and by planning carefully and systematically for the human capital challenges looming near for all of the Federal service.

THE CHALLENGE OF IMPROPER PAYMENTS

Benefits of the Federal nutrition assistance programs must be carefully targeted and delivered to those who are eligible, in need, and wish to participate. Benefit

payments made in error increase the cost of these programs to the taxpayers and can divert needed assistance from eligible participants seeking services. Today I am pleased to report to you, for the second year in a row, record high payment accuracy rates for the Food Stamp Program. In fiscal year 2002, the most recent year for which data is available, the Food Stamp Program achieved an accuracy rate of 91.74 percent, 0.4 percent higher than fiscal year 2001's record achievement. Despite this success, much remains to be done to improve the accuracy and efficiency of benefit delivery in all the Federal nutrition assistance programs, not just the Food Stamp Program. The President's budget requests additional funding to strengthen integrity and program management both at the Federal and State levels. Our request includes an increase of $7 million in our administrative budget which will be targeted at maintaining our continuing success in the Food Stamp Program, improving the accuracy of certifications for free and reduced price school meals, and improving delivery of program benefits and reinvigorating our oversight, training and technical assistance activities for our State and local partners.

BUDGET AND PERFORMANCE INTEGRATION

The President's Management Agenda recognizes that good decision-making depends on both the availability of relevant, high quality data and using that information in an analytical, business-like approach to problem solving. The Food and Nutrition Service has long been a leader in the Federal arena. Our entitlement programs are performance funded. This requires us to balance, through analysis and insight, an uncertain dynamic program demand with the constraints of a fixed appropriation. In this year's budget explanatory notes, you will find expanded performance information and analysis with clear connections linking USDA's strategic plan, our budget request, and program performance.

Vital to the success of the President's vision of improved Federal decision-making and seamless budget and performance integration is an adequately funded, properly positioned agenda of performance measurement and program assessment. Funding proposed in the request would support a range of important program assessment activities: focused studies of program operations, development of comprehensive measures of program performance to inform and foster outcome-based planning and management; and technical assistance to States and communities for practical demonstrations of potential policy and program improvements. These activities provide a crucial foundation for strategic planning and program innovation. This request will allow the programs to respond to emerging performance management issues identified by the Performance Assessment Rating Tool of the National School Lunch Program and Food Stamp Program as well as support effective stewardship of the taxpayer investment in nutrition assistance.

REACHING OUT TO THOSE IN NEED THROUGH FAITH-BASED AND OTHER COMMUNITY ORGANIZATIONS

To meet our commitment to improve access for all who are eligible, we must work closely with our program partners—individuals and organizations in communities across America who deliver the Federal nutrition assistance programs, and work to make them accessible and effective. Faith-based organizations have long played an important role in raising community awareness about program services, assisting individuals who apply for benefits, and delivering benefits. President Bush has made working with the faith-based community an Administration priority, and we intend to continue our outreach efforts in fiscal year 2005. The partnership of faith-based organizations and FNS programs, including TEFAP, WIC, NSLP, and the CSFP, is long-established. Indeed, the majority of organizations such as food pantries and soup kitchens that actually deliver TEFAP benefits are faith-based. Across the country, faith-based organizations have found over the years that they can participate in these programs without compromising their mission or values. They are valued partners in an effort to combat hunger in America.

HUMAN CAPITAL MANAGEMENT

The General Accounting Office (GAO), have demonstrated that recruiting, developing and retaining a highly-skilled workforce is critical to sustaining our public service. This is especially true for the Food and Nutrition Service. We currently estimate that up to 80 percent of our senior leaders are eligible to retire within five years, as is nearly 30 percent of our total workforce. FNS must address this serious challenge by improving the management of the agency's human capital, strengthening services provided to employees, and implementing programs designed to improve the efficiency, diversity, and competency of the work force. With just nominal increases for basic program administration in most years, the Food and Nutrition

Service has reduced its Federal staffing levels significantly over time. We have compensated for these changes by working smarter—re-examining our processes, building strong partnerships with the State and local entities which administer our programs, and taking advantage of technological innovations. We are extremely proud of what we have accomplished, but seek additional funding in a few targeted areas to address specific vulnerabilities. Full funding of the nutrition programs administration requested in the President's budget, approximately 0.39 percent of our program portfolio, is vital to our continued success.

Now, I would like to review some of the components of our request that relate to these outcomes under each program area.

FOOD STAMP PROGRAM

The President's budget requests $33.6 billion for the Food Stamp account including the Food Stamp Program and its associated nutrition assistance programs. These resources will serve an estimated 24.9 million people each month participating in the Food Stamp Program alone. Included in this amount, we propose to continue the $3 billion contingency reserve provided for the program in fiscal year 2004. The importance of this reserve is especially critical in fiscal year 2005. While we anticipate that the improvement we are now seeing in the general economy will at some point begin to impact the program, predicting the turning point of participation is challenging. Our request also presents, as an alternative to the traditional contingency reserve, a proposal of indefinite authority for program benefits and payments to States and other non-Federal entities.

CHILD NUTRITION PROGRAMS

The budget requests $11.4 billion for the Child Nutrition Programs, which provide millions of nutritious meals to children in schools and in childcare settings every day. This level of funding will support an increase in daily School Lunch Program participation from the current 28.7 million children to over 29.2 million children. This funding request also supports an increase in daily School Breakfast Program participation from the current 8.8 million to 9.0 million children. Requested increases in these programs also reflect rising school enrollment, increases in payment rates to cover inflation, and proportionately higher levels of meal service among children in the free and reduced price categories. We are proposing to extend provisions that would expire on March 31, 2004.

WIC

The President's budget includes $4.8 billion for the Special Supplemental Nutrition Program for Women, Infants and Children, the WIC program. The request will allow local communities to provide food, nutrition education, and a link to health care to a monthly average of 7.86 million needy women, infants and children during fiscal year 2005. We also propose to continue our vital initiatives, begun in fiscal year 2004, to enhance breastfeeding initiation and duration, improve State information technology infrastructure, and to maximize WIC's potential to combat childhood obesity. The $125 million contingency fund provided for in the fiscal year 2003 appropriation continues to be available to the program. These resources are available if costs exceed current estimates.

COMMODITY SUPPLEMENTAL FOOD PROGRAM (CSFP)

The Commodity Supplemental Food Program (CSFP) serves elderly persons and at risk low-income pregnant and post-partum and breastfeeding women, infants and children up to age six. The budget requests $98.3 million for this program, the same level appropriated in fiscal year 2004. This request may not support the same level of program services as in fiscal year 2004 due to the availability of one-time carryover funds from 2003. However, we will take all available administrative actions to minimize any program impact. We face a difficult challenge with regard to discretionary budget resources. CSFP operates in selected areas in 32 States, the District of Columbia, and two Indian Tribal Organizations. The populations served by CSFP are eligible to receive similar benefits through other Federal nutrition assistance programs. We believe our limited resources are best focused on those program available in all communities nationwide.

THE EMERGENCY FOOD ASSISTANCE PROGRAM (TEFAP)

As provided for in the Farm Bill, the budget requests $140 million for commodities in this important program. Our request for States' storage and distribution costs, critical support for the Nation's food banks, is $50 million. The Food and Nu-

trition Service is committed to ensuring the continuing flow of resources to the food bank community including directly purchased commodities, administrative funding, and surplus commodities from the USDA market support activities. Surplus commodity donations significantly increase the amount of commodities that are available to the food bank community from Federal sources.

NUTRITION PROGRAMS ADMINISTRATION (NPA)

We are requesting $152.2 million in this account, which includes an increase of $7 million for the program integrity initiative described earlier. Included are also a number of initiatives, under the Food and Nutrition Service and the Center for Nutrition Policy and Promotion, designed to combat obesity and improve the dietary quality of all Americans. Our total request for Federal administrative resources represents only about 0.39 percent of the program resources for which we have responsibility and sustains the program management and support activities of our roughly 1,545 employees nationwide. I believe we need these modest increases in funding in order to maintain accountability for our $50 billion portfolio and to assist States to effectively manage the programs and provide access to all eligible people.

Thank you for the opportunity to present this written testimony.

Senator BENNETT. Thank you very much. Mr. Hawks.

STATEMENT OF WILLIAM T. HAWKS

Mr. HAWKS. Thank you, Mr. Chairman, Senator Kohl.

It is indeed a pleasure to be with you today to discuss the activities of the Marketing and Regulatory Programs.

Senator BENNETT. Would you pull the microphone a little closer to you?

Mr. HAWKS. Turning it on will help, as well.

Senator BENNETT. That also helps.

Mr. HAWKS. As I said, it is certainly a pleasure to be with you today to discuss the activities of the Marketing and Regulatory Programs and the 2005 budget for those agencies within Marketing and Regulatory Programs. Those are the Animal and Plant Health Inspection Service, Agricultural Marketing Service and the Grain Inspection, Packers and Stockyards Administration.

My motto has been working together works. I am holding my agencies accountable to make sure that they work.

I have five goals that I hold them accountable for. The first one is to build broader bridges. The second one is to move more product. The third goal is to invest in infrastructure. The fourth goal is to grow our people. The fifth goal is to sell agriculture as a profession.

The Marketing and Regulatory Program activities are funded both by beneficiaries of the program services and by the taxpayers. They carry out programs costing nearly $1.8 billion with $418 million funded by fees paid by the beneficiaries of the services and $449 million collected from Customs receipts.

On the appropriations side, the APHIS is requesting $893 million, GIPSA is requesting $44 million, and AMS is requesting $87 million.

APHIS' primary mission is to safeguard animal and plant health, address conflicts with wildlife, faciliate safe Agricultural trade, promote environmental stewardship, and improve animal well being. APHIS has been working to enhance an already vigilant animal and plant health monitoring system. APHIS trade issues resolution management efforts enabled us to negotiate fair trade in the international market. APHIS also regulates the movement and field release of biotechnology derived plants. Recent developments in bio-

technology hold great promise as long as we are able to ensure the protection of the environment and the safety of the foods.

GIPSA facilitates the marketing of livestock, meat, poultry, cereals, oil seeds and related agricultural products and promotes fair and competitive trade. GIPSA is requesting increased funding for strengthening efforts to resolve international grain trade issues and to provide improved technology for the evaluating the value of livestock carcasses.

AMS activities assist U.S. agricultural industry in marketing their products and in finding ways to improve their profitability. AMS budget request seeks an increase of $10 million of appropriated funds to begin investing in a new multi-agency web-based supply chain management system to manage purchases of $2.5 billion of commodities used in all food assistance programs every year. When fully implemented, this system will decrease the time for purchases from 24 days down to 5 days.

PREPARED STATEMENTS

In light of time, this is going to conclude my statement. You have my full written statement and I look forward to responding to questions.

Senator BENNETT. Thank you very much.

For the record, without objection, the written statement of all of you will be included in the record. Dr. Murano.

[The statements follow:]

PREPARED STATEMENT OF WILLIAM T. HAWKS

Mr. Chairman and members of the Committee, I am pleased to appear before you to discuss the activities of the Marketing and Regulatory Programs of the U.S. Department of Agriculture and to present our fiscal year 2005 budget proposals for the Animal and Plant Health Inspection Service (APHIS), the Grain Inspection, Packers and Stockyards Administration (GIPSA), and the Agricultural Marketing Service (AMS).

With me today are Dr. Charles Lambert, Deputy Under Secretary for MRP; Mr. Peter Fernandez, Associate Administrator of APHIS; Mrs. Donna Reifschneider, Administrator of GIPSA, and Mr. A.J. Yates, Administrator of AMS. They have statements for the record and will answer questions regarding specific budget proposals.

Under my leadership, the Marketing and Regulatory Programs have addressed several broad goals and objectives to increase marketing opportunities and to protect American agriculture from damages caused by pests and diseases.

Building Broader Bridges.—We strengthened cooperation and strategic partnerships with farmers and ranchers, States, foreign governments, congressional offices, agricultural commodity and industry associations, agricultural scientific groups, and other interested parties. We want to ensure that our policies and programs provide the most benefits they can to the affected people which demonstrates that working together works.

Moving More Product.—We expanded domestic and international market opportunities for U.S. agriculture products including value enhanced products and products of biotechnology. We have worked closely with the Foreign Agricultural Service and the U.S. Trade Representative to aggressively and creatively resolve sanitary, phytosanitary, biotechnology, grain inspection, commodity grading and other trading issues that limit our potential for growth in international trade.

Investing in Infrastructure.—We invested in stronger border security, pest and disease surveillance and monitoring, laboratory capacity such as the National Veterinary Science Lab in Ames, Iowa. We increased market news on export markets, made improvements in e-Government, enhanced investigations of anti-competitive market practices and provided greater support for biotechnology. Agriculture that is healthy, both biologically and economically, is a marketable agriculture.

Growing Our People.—We made a concerted effort to recruit, recognize and reward accomplishment and inspire current and future leaders within MRP. We are

making MRP a place where the best and brightest want to be, including promising men and women in diverse fields such as journalism, accounting, and economics.

Selling Agriculture as a Profession.—We are creatively marketing the vital role that agriculture plays in every American's life to assist our efforts to recruit and retain the highest caliber workforce for MRP and USDA.

FUNDING SOURCES

The Marketing and Regulatory Program activities are funded by both the taxpayers and beneficiaries of program services. The budget proposes that the MRP agencies carry out programs costing $1.8 billion; with $418 million funded by fees charged to the direct beneficiaries of MRP services and $449 million from Customs receipts.

On the appropriation side, under current law, the Animal and Plant Health Inspection Service is requesting $828 million for salaries and expenses and $5 million for repair and maintenance of buildings and facilities; the Grain Inspection, Packers and Stockyards Administration is requesting $44 million, and the Agricultural Marketing Service is requesting $87 million.

The budget again proposes user fees that, if enacted, would recover about $40 million. Legislation was submitted in 2003 which would authorize new license fees to recover the cost of administering the Packers and Stockyards (P&S) Act and authorize additional grain inspection fees for developing grain standards. Legislation will be submitted soon to enable additional license fees for facilities regulated under the Animal Welfare Act. I will use the remainder of my time to highlight the major activities and our budget requests for the Marketing and Regulatory Programs.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

The fundamental mission of APHIS is to anticipate and respond to issues involving animal and plant health, conflicts with wildlife, environmental stewardship, and animal well-being. Together with their customers and stakeholders, APHIS promotes the health of animal and plant resources to facilitate their movement in the global marketplace and to ensure abundant agricultural products and services for U.S. customers. We believe that safeguarding the health of animals, plants, and ecosystems makes possible safe agricultural trade and reduces losses to agricultural and natural resources.

APHIS builds bridges by working in concert with its stakeholders—States, Tribes, industry, and the public—to maintain and expand export market opportunities and to prevent the introduction and/or to respond to new threats of plant and animal pests and diseases. APHIS invests in the agricultural marketing infrastructure that helps protect the agricultural sector from pests and diseases while at the same time moving more U.S. product.

I would like to highlight some key aspects of the APHIS programs:

Safeguarding the Agricultural Sector and Resource Base.—While APHIS continues to work closely with the Department of Homeland Security (DHS) to exclude agricultural health threats, it retains responsibility for promulgating regulations related to entry of passengers and commodities into the United States. APHIS' efforts have helped keep agricultural health threats away from U.S. borders through increased offshore threat-assessment and risk-reduction activities. APHIS has also increased an already vigilant animal and plant health monitoring and surveillance system to promptly detect outbreaks of foreign and endemic plant and animal pests and diseases.

Management Programs.—Because efforts to exclude foreign pests and diseases are not 100 percent successful, APHIS also assists stakeholders in managing new and endemic agricultural health threats, ranging from threats to aquaculture to cotton and other crops, tree resources, livestock and poultry. In addition, APHIS assists stakeholders on issues related to conflicts with wildlife and animal welfare.

Moving More Product.—The Trade Issues Resolution and Management efforts are key to ensuring fair trade of all agricultural products. APHIS' staff negotiates sanitary and phytosanitary (SPS) standards, resolves SPS issues, and provides clarity on regulating imports and certifying exports which improves the infrastructure for a smoothly functioning market in international trade. Ensuring that the rules of trade are based on science helps open markets that have been closed by unsubstantiated SPS concerns. APHIS' efforts contributed to the opening or retention of $2.5 billion in export markets in fiscal year 2003 by helping resolve individual trade issues abroad.

Biotechnology.—Recent developments in biotechnology underscore the need for effective regulation to ensure protection of the environment and food supply, reduce market uncertainties, and encourage development of a technology that holds great

promise. APHIS' Biotechnology Regulatory Services unit coordinates our services and activities in this area and focuses on both plant-based biotechnology and transgenic arthropods. We also are examining issues related to transgenic animals.

APHIS' 2005 BUDGET REQUEST

In a year of many pressing high-priority items for taxpayer dollars, the budget request proposes about $828 million for salaries and expenses. There are substantial increases to support the Administration's Food and Agriculture Defense Initiative and to protect the agriculture sector from bovine spongiform encephalopathy (BSE). A brief description of key initiatives follows.

A total of about $173 million for Foreign Pest and Disease Exclusion.—Efforts will be focused on enhancing our ability to exclude Mediterranean fruit fly and foreign animal diseases. We also request funds to regulate the possession and transfer of Select Agents, toxins and pathogens necessary for research and other beneficial purposes which could be deadly in the hands of terrorists.

A total of about $224 million for Plant and Animal Health Monitoring.—APHIS plays a critical role in protecting the Nation from deliberate or unintentional introduction of an agricultural health threat, and the budget requests $94 million, a $49 million increase, as part of the Food and Agriculture Defense Initiative. This includes initiatives that enhance plant and animal health threat monitoring and surveillance; bolster a National Animal Identification Program; ensure greater cooperative surveillance efforts with States; improve connectivity with the integration and analysis functions at DHS for plant and animal health threats; and boost animal vaccine availability; and other efforts. In addition, $50 million is requested for bovine spongiform encephalopathy (BSE) activities to accelerate the development of a National animal ID effort and to increase testing to detect the presence of BSE in the U.S. livestock herd.

A total of $320 million for pest and disease management programs.—Once pests and disease are detected, prompt eradication reduces longterm damages. In cases where eradication is not feasible (e.g., European gypsy moth), attempts are made to slow the advance, and damages, of the pest or disease. APHIS provides technical and financial support to help control or eradicate a variety of agricultural threats.

The budget proposes $57 million of increased funding for efforts against low-pathogenic avian influenza, emerging plant pests (such as Citrus Canker and Emerald Ash Borer), tuberculosis, scrapie, and chronic wasting disease.

Other programs offer offsets to those increases. Successes in boll weevil eradication efforts allow a reduction in that program. Decreased funding is requested for Asian Long-horned Beetle based on the ongoing levels of State contributions. Funding is reduced for Johne's Disease since it is rather endemic and funds need to be rationed for other program needs. The budget also assumes that State cooperators will fund a greater share of wildlife management programs.

A total of $17 million for the Animal Care programs.—APHIS will maintain its animal welfare and horse protection programs. The budget includes a proposal, similar to fiscal year 2004, to collect $10.9 million in additional fees charged to facilities and establishments required to be registered under the Animal Welfare Act but not currently subject to a fee. This includes research facilities, carriers, and in-transit handlers of animals. Since these facilities are the direct beneficiaries of taxpayer assistance, it is appropriate that a portion of the costs be funded by these beneficiaries.

A total of about $82 million for Scientific and Technical Services.—Within USDA, APHIS has chief regulatory oversight of genetically modified organisms. To help meet the needs of this rapidly evolving sector, the budget includes a request to, in part, enhance the regulatory oversight of field trials of crops derived with biotechnology. Also, APHIS develops methods and provides diagnostic support to prevent, detect, control, and eradicate agricultural health threats, and to reduce wildlife damages (e.g., coyote predation). It also works to prevent worthless or harmful animal biologics from being marketed.

A total of $12 million for management initiatives.—This includes building upon efforts started with Homeland Security Supplemental funds for improving physical and operational security, It also includes providing the State Department funds to help cover higher security costs for APHIS personnel abroad. A portion of the increase would also be used for enhanced computer security and eGov initiatives.

GRAIN INSPECTION, PACKERS AND STOCKYARDS ADMINISTRATION

GIPSA's mission is to facilitate the marketing of livestock, meat, poultry, cereals, oilseeds, and related agricultural products and to promote fair and competitive trade for the benefit of consumers and American agriculture. It helps move more U.S.

product both domestically and abroad by investing in domestic infrastructure that supports marketing within the grain and livestock industry. GIPSA fulfills this through both service and regulatory functions in two programs: the Packers and Stockyards Programs (P&SP) and the Federal Grain Inspection Service (FGIS).

Packers and Stockyards Programs.—The strategic goal for P&SP is to promote a fair, open and competitive marketing environment for the livestock, meat, and poultry industries. Currently, with 166 employees, P&SP monitors the livestock, meatpacking, and poultry industries, estimated by the Department of Commerce to have an annual wholesale value of over $118 billion. Legal specialists and economic, financial, marketing, and weighing experts work together to monitor emerging technology, evolving industry and market structural changes, and other issues affecting the livestock, meatpacking, and poultry industries that the Agency regulates.

We conducted over 1,700 investigations in fiscal year 2003 to enforce the Packers and Stockyards Act for livestock producers and poultry growers, of which about 95 percent were closed in a year. Financial recoveries were $27.2 million.

The Swine Contract Library began operation on December 3, 2003. Producers can see contract terms, including, but not limited to, the base price determination formula and the schedules of premiums or discounts, and packers' expected annual contract purchases by region. Since December 3, GIPSA has experienced approximately 27 "hits" each day to view the Contract Summary reports and approximately 6 "hits" per day to view the Monthly reports.

Federal Grain Inspection Service.—FGIS facilitates the marketing of U.S. grain and related commodities under the authority of the U.S. Grain Standards Act and the Agricultural Marketing Act of 1946. As an impartial, third-party in the market, we advance the orderly and efficient marketing and effective distribution of U.S. grain and other assigned commodities from the Nation's farms to domestic and international buyers. We are part of the infrastructure that undergirds the agricultural sector.

GIPSA works with government and scientific organizations to establish internationally recognized methods and performance criteria and standards to reduce the uncertainty associated with testing for the presence of biotechnology grains and oil seeds. It also provides technical assistance to exporters, importers and end users of U.S. grains and oilseeds, as well as other USDA agencies, USDA Cooperator organizations, and other governments. These efforts help facilitate the sale of U.S. products in international markets.

Our efforts to improve and streamline our programs and services are paying off for our customers, both in terms of their bottom lines and in greater customer satisfaction. FGIS' service delivery costs average $0.30 per metric ton, or approximately 0.23 percent of the $14 billion value of U.S. grain exports. In fiscal year 2003 alone, more than 1.8 million inspections were performed on more than 222 million tons of grains and oilseeds.

One indicator of the success of our outreach and educational initiatives is the number of foreign complaints lodged with FGIS regarding the quality or quantity of U.S. grain exports. In fiscal year 2003, FGIS received only 13 quality complaints and no quantity complaints from importers on grains inspected under the U.S. Grain Standards Act. These involved 229,587 metric tons, or about 0.2 percent by weight, of the total amount of grain exported during the year.

GIPSA'S 2005 BUDGET REQUEST

For 2005, the budget proposes a program level for salaries and expenses of $44 million. Of this amount, $20 million is devoted to grain inspection activities for standardization, compliance, and methods development and $24 million is for Packers and Stockyards Programs.

The 2005 budget includes the following program increases:

—$1 million for rapid response teams to closely examine livestock marketing to ensure that producers are not unfairly disadvantaged by the BSE situation. USDA will use the funds to conduct market surveillance and ensure that marketing and procurement contracts are honored in the aftermath of the BSE finding.

—About $5 million to significantly upgrade the agency's IT functions, including the ability to securely accept, analyze, and disseminate information relevant to the livestock and grain trades. About $4 million is a one-time increase for investment. Currently, GIPSA receives more than 2.5 million submissions from stakeholders, all of which are done on paper. The request also includes $150,000 to maintain the Swine Contract Library.

—$1.2 million to monitor the various technologies that livestock and meatpacking industries use to evaluate carcasses to ensure fair and consistent use of those

technologies. Producer compensation is increasingly dependent not simply on the weight of the animals they bring to slaughter, but the characteristics of the carcasses as well (e.g., fat content).

—$0.5 million to enable GIPSA to better address and resolve international grain trade issues, thus precluding disruption of U.S. exports. GIPSA has experienced a growing demand for cooperative participation with other agencies with international trade responsibilities to help expand markets for U.S. agricultural products and removing barriers to trade.

New User fees.—New user fees, similar to those proposed for fiscal year 2004, would be charged to recover the costs of developing, reviewing, and maintaining official U.S. grain standards used by the grain industry. Those who receive, ship, store, or process grain would be charged fees estimated to total about $6 million to cover these costs. Also, the Packers and Stockyards program would be funded by new license fees of about $23 million that would be required of packers, live poultry dealers, stockyard owners, market agencies and dealers, as defined under the Packers and Stockyards Act.

AGRICULTURAL MARKETING SERVICE

The mission of the AMS is focused on facilitating the marketing of agricultural products in the domestic and international marketplace, ensuring fair trading practices, and promoting a competitive and efficient marketplace to the benefit of producers, traders, and consumers of U.S. food and fiber products. The Agency accomplishes this mission through a wide variety of publicly and user funded activities that help their customers improve the marketing of their food and fiber products and ensure that food and fiber products remain available and affordable to consumers. The following are just some of the ways that AMS is doing its job better in serving its customers.

Customer Service and Technology.—AMS continues to improve its service delivery by taking advantage of new technology to improve public electronic access to information and services and to increase operational efficiency. For example, the Livestock Mandatory price reporting system processes huge amounts of raw data received from slaughter facilities that report their transactions involving purchases of livestock and sales of boxed beef and lamb, lamb carcasses, and imported boxed lamb cuts. These data, including prices, contracts for purchase, and other related information, are publicly disseminated in over 100 daily, weekly, and monthly reports on fed cattle, swine, lamb, beef and lamb meat. AMS continues to make enhancements to existing reports and to introduce new reports in consultation with industry stakeholders.

In 2003, AMS began offering automatic e-mail delivery of comprehensive Market News information to subscribers. This free email subscription service, provided in partnership with the Mann Library at Cornell University, provides access to nearly 1,500 daily, weekly and monthly market reports covering the six major AMS commodity groups. AMS also is developing a Market News web portal that will allow users to establish their own unique web pages through which they can immediately access preferred market news reports, have the capability to build specialized reports, and add customized features including nationwide weather reports and metric data conversions. Users will be able to access 5 years of data and download it in usable formats, including charts, spreadsheets, and graphs. The portal will be available to public users later this year for fruit and vegetable reports, and they hope to expand it to market reports for other commodities soon thereafter.

Partnerships.—AMS depends on strong partnerships with cooperating State agencies and other Federal agencies to carry out many of our programs. State agency partners collect data, provide inspection, monitoring, and laboratory services for AMS, and otherwise maximize the value of both State and Federal resources through sharing and coordination. For instance, AMS' Market News program maintains cooperative agreements with 40 States to coordinate local market coverage with the regional and national coverage needed for AMS market reporting. State employees who inspect shipments of seed within a State provide information on potential violations in interstate shipments to AMS' Federal Seed program. Thirty-three States and territories participate with AMS in Pesticide Recordkeeping education and record inspection activities and are reimbursed for their services. Furthermore, the Pesticide Data program depends on its 10–12 State and three Federal partners to collect and test the product samples on which the program results are based. In fact, the Pesticide Data program directs 80 percent of its funding to its State partners in reimbursement for services provided. Another source of support for State agriculture programs is AMS' Federal-State Marketing Improvement Program (FSMIP), otherwise known as the Payments to States Program. In 2003, AMS

allocated FSMIP grant funds to 20 States for 28 projects of local and regional importance, such as marketing studies or developing innovative approaches to the marketing of agricultural products.

Under the National Organic program, AMS program personnel accredit State, private, and foreign certifying agents who certify that organic production and handling operations are in compliance with the national organic standards. As of February 2004, AMS received 137 applications for accreditation. Of these, the program has thus far accredited a total of 90 certifying agents, including 15 States, and 37 foreign certifying agents. AMS also administers two cost share programs through agreements with the States that help to offset certification costs for organic producers. Additional resources provided in fiscal year 2004 will allow us to strengthen our support of the National Organic Standards Board activities, including technical advisory panel evaluations of materials and program evaluations—or peer reviews—and to strengthen program enforcement.

Market Analysis.—In 2003, AMS supported wholesale or farmers market facility projects in Mississippi, Georgia, Florida, Oregon, Arizona, New York, Texas, American Samoa, Hawaii, and Kentucky. AMS also supports marketing and market technology research projects which were presented at numerous marketing conferences and workshops. AMS supports farmers markets by conducting research on emerging trends in market operations and practices and providing research reports, reference material and fact sheets to farm vendors, farm market managers, and the general public through the AMS website and a telephone hotline.

AMS' Transportation Services Program works with Federal, State, and local policy-makers to maintain an efficient national transportation system that supports the needs of farmers, agricultural shippers, and rural America. AMS conducts and sponsors economic studies of domestic and international transportation issues and provides technical assistance and information to producers, shippers, carriers, government agencies, and universities. Program experts have generated studies and reports on U.S. waterways, rail lines and rail car availability; rail and shipping rate analyses; geographically disadvantaged farmers and ranchers, and many others.

AMS transportation specialists are often called upon to provide information and advice when agricultural transportation is disrupted. After September 11, 2001, AMS has increasingly been asked to provide more analyses on transportation security for agricultural products. In 2003, AMS developed a Transportation Security Briefing Book using the information currently available. The book provides an overview of the agricultural transportation system, existing safety measures, and discusses the adverse effects of past disruptions in the system. While this is a good start, we have found that much more study is needed in this area for all modes of transport, but particularly for trucking, which moves 90 percent of agricultural freight for at least one segment of its transportation to destination.

Commodity Purchases.—AMS works in close cooperation with both the Food and Nutrition Service (FNS) and the Farm Services Agency (FSA) to administer USDA commodity purchases that stabilize markets and support nutrition programs, such as the National School Lunch Program, the Emergency Food Assistance Program, the Commodity Supplemental Food Program, and the Food Distribution Program on Indian Reservations. To maximize the efficiency of food purchase and distribution operations, AMS, FNS, and FSA each provide a component of program administration according to their organizational structure and expertise, but the system is complex and requires close coordination. To better coordinate the operations between the three agencies and control the vast array of details inherent to the procurement process, the Processed Commodities Inventory Management System (PCIMS) was developed more than 10 years ago to track bids, orders, purchases, payments, inventories, and deliveries of approximately $2.5 billion of commodities used in all food assistance programs every year and another $1 billion in price support commodity products maintained in inventory. PCIMS is still being used by the three agencies with modifications having been made over the years, when feasible, to add capabilities such as financial tracking or to meet changes in program delivery.

AMS' 2005 BUDGET REQUEST

For AMS, the budget proposes a program level of $732 million, of which over 88 percent will be funded by user fees and Section 32 funds. The budget requests an appropriation of $87 million for Marketing Services and Payments to States. The 2005 budget includes an increase of $10 million in appropriated funds to improve the information technology systems used to manage and control commodity orders, purchases, and delivery. Under this proposal, PCIMS would be replaced by the Web-based Supply Chain Management System (WBSCM). Implementation of WBSCM

will improve the efficiency of Federal procurement of commodities by reducing ordering and delivery times from 24 days to 5 days. The 2005 budget also includes an increase of $0.3 million to conduct studies aimed at improving the security of the U.S. transportation system for agricultural commodities and supplies. The budget includes a decrease of $2 million for FSMIP to reflect a reduction for a one-time increase in 2004 for creation of specialty markets in Wisconsin.

CONCLUSION

This concludes my statement. I am looking forward to working with the Committee on the 2005 budget for the Marketing and Regulatory Programs. We believe the proposed funding amounts and sources of funding are vital to protecting American agriculture from pests and diseases, both unintentional and those caused by terrorist action, and for moving more product to foreign markets. It will provide the level of service expected by our customers—the farmers and ranchers, the agricultural marketing industry, and consumers. We are happy to answer any questions.

PREPARED STATEMENT OF A.J. YATES, ADMINISTRATOR, AGRICULTURAL MARKETING SERVICE

Mr. Chairman and Members of the Committee, I am pleased to have this opportunity to represent the Agricultural Marketing Service in presenting our fiscal year 2005 budget proposal. To provide some context for our budget proposal, I would like to begin by reviewing our agency's mission and describing some of the customer service improvements we have made in delivery of our programs.

MISSION

The mission of the Agricultural Marketing Service—AMS—is focused on marketing: to facilitate the marketing of agricultural products in the domestic and international marketplace, ensure fair trading practices, and promote a competitive and efficient marketplace to the benefit of producers, traders, and consumers of U.S. food and fiber products.

We accomplish this mission through a wide variety of publicly funded activities that help our customers better market their food and fiber products and ensure that food and fiber products remain available and affordable to consumers. More specifically, AMS helps to make the nation's agricultural markets work efficiently by providing wide and equal access to market information for all producers and traders; by developing agricultural product descriptions that provide a common language for commercial trade; by providing data on pesticide residues and microbiological pathogens that support science-based risk assessment; by providing "how to" technical expertise to growers, transporters, and others in the marketing chain; and by helping to develop alternative or improved market outlets.

AMS also offers voluntary fee-based services such as product quality grading, contract certification, export verification, and quality control services such as plant inspections, equipment reviews, and production quality or process control certification. Because these voluntary services are available to verify the quality of agricultural products and the efficacy of production processes, they support private contractual arrangements and marketing claims that can improve profitability for U.S. producers in both domestic and international markets. In delivering these voluntary services, we remain vigilant about their costs, while working in partnership with our customers to ensure that marketplace needs are met.

CUSTOMER SERVICE AND TECHNOLOGY

We continue to improve our service delivery by taking advantage of new technology—to improve public electronic access to information and services and to increase our operational efficiency. For example, the Livestock Mandatory price reporting system processes huge amounts of raw data—some 2 to 3 million data items each week—received from 112 slaughter facilities, that report their transactions involving purchases of livestock and sales of boxed beef and lamb, lamb carcasses, and imported boxed lamb cuts. These data, including prices, contracts for purchase, and other related information, are publicly disseminated in over 100 daily, weekly, and monthly reports on fed cattle, swine, lamb, beef and lamb meat. AMS continues to make enhancements to existing reports and to introduce new reports in consultation with industry stakeholders.

In 2003, AMS began offering automatic email delivery of comprehensive Market News information to subscribers. Market News reports cover prices, volume, quality, condition, and other market data on farm products in production areas and at spe-

cific domestic and international markets. This free email subscription service, provided in partnership with the Mann Library at Cornell University, provides access to nearly 1,500 daily, weekly and monthly market reports covering the six major AMS commodity groups—cotton, dairy, fruit and vegetable, livestock and seed, poultry, and tobacco. Users can search by keyword or browse by commodity, then subscribe to and receive selected reports via email whenever an update is published. This initiative is part of the Federal e-government effort to streamline government-to-citizen communications.

AMS also is developing a Market News web portal that will allow users to establish their own unique web pages through which they can immediately access preferred market news reports, have the capability to build specialized reports, and add customized features including nationwide weather reports and metric data conversions. Users will be able to access 5 years of data and download it in usable formats, including charts, spreadsheets, and graphs. The portal will be available to public users later this year for fruit and vegetable reports, and we hope to expand it to market reports for other commodities soon thereafter.

PARTNERSHIPS

AMS depends on strong partnerships with cooperating State agencies and other Federal agencies to carry out many of our programs. State agency partners collect data, provide inspection, monitoring, and laboratory services for AMS, and otherwise maximize the value of both State and Federal resources through sharing and coordination. For instance, AMS' Market News program maintains cooperative agreements with 40 States to coordinate local market coverage with the regional and national coverage needed for AMS market reporting. State employees who inspect shipments of seed within a State provide information on potential violations in interstate shipments to AMS' Federal Seed program. Thirty-three States and territories participate with AMS in Pesticide Recordkeeping education and record inspection activities and are reimbursed for their services. Furthermore, our Pesticide Data program depends on its State and Federal partners to collect and test the product samples on which the program results are based. In fact in fiscal year 2004, the Pesticide Data program will direct about 80 percent of its funding to its eleven State partners in reimbursement for services provided. The resulting information generated by AMS can be utilized by other Federal agencies such as EPA and FDA for policy and regulatory actions, as well as other USDA agencies, academia, agricultural industry, international organizations, and global traders.

We work with local and city agencies to improve wholesale, farmers, and other direct marketing opportunities. In 2003, our Wholesale, Farmers, and Alternative Markets program supported wholesale or farmers market facility projects in Mississippi, Georgia, Florida, Oregon, Arizona, New York, Texas, American Samoa, Hawaii, and Kentucky. The program also supports marketing and market technology research projects as well as numerous marketing conferences and workshops. In an effort to help link farm direct sales with school nutrition programs, for example, AMS organized a workshop focused on farm to school marketing in fiscal year 2003 at the first national "Farm to Cafeteria Conference" in Seattle, Washington.

Farmers markets directly benefit local producers and continue to be an important farm product outlet for agricultural producers nationwide. Farmers markets have risen in popularity due to growing consumer interest in obtaining fresh products directly from the farm. The number of farmers markets has grown by 79 percent between 1994 and 2002 to more than 3,100 facilities nationwide. AMS supports farmers markets by conducting research on emerging trends in market operations and practices and providing research reports, reference material and fact sheets to farm vendors, farm market managers, and the general public through the AMS website and a telephone hotline. We also participate in industry, producer, and academic conferences and training sessions across the country.

Another source of support for local agriculture programs is AMS' Federal-State Marketing Improvement Program, or FSMIP. These matching grant funds, made available to State departments of agriculture and other State agencies, fund 25 to 35 projects each year. In 2003, we allocated FSMIP grant funds to 20 States for 28 projects of local and regional importance, such as marketing studies or developing innovative approaches to the marketing of agricultural products.

Our National Organic program, in partnership with its advisory committee, provides nationwide standards and a certification system for the U.S. organic food industry, which has over $8 billion in sales and has seen annual growth in excess of 22 percent. Between 1995 and 2000, the U.S. organic market expanded by 175 percent and is expected to more than double its 2000 value of $7.8 billion to approximately $16 billion by 2005. AMS works with the National Organic Standards Board

to develop standards for substances used in organic production, maintain a National List of approved and prohibited substances for organic production, and convene technical advisory panels to provide scientific evaluation of materials considered for the National List. AMS program personnel accredit State, private, and foreign certifying agents who certify that organic production and handling operations are in compliance with the national organic standards. As of February 2004, AMS received 137 applications for accreditation. Of these, the program has thus far accredited a total of 90 certifying agents—53 domestic certifying agents, including 15 States, and 37 foreign certifying agents. AMS also administers two cost share programs through agreements with the States that help to offset certification costs for organic producers. Additional resources provided in fiscal year 2004 will allow us to strengthen our support of Board activities, including technical advisory panel evaluations of materials and program evaluations—or peer reviews—and to strengthen program enforcement.

Our Transportation Services Program works with Federal, State, and local policymakers to maintain an efficient national transportation system that supports the needs of farmers, agricultural shippers, and rural America. The program helps to support farm income, expand exports, and maintain the flow of food to consumers. AMS conducts and sponsors economic studies of domestic and international transportation issues and provides technical assistance and information on agricultural transportation, rural infrastructure and access, and food distribution to producers, shippers, carriers, government agencies, and universities. Program experts have generated studies and reports on U.S. waterways, rail lines and rail car availability; rail and shipping rate analyses; and geographically disadvantaged farmers and ranchers, and many others. The program also produces periodic publications that provide information for agricultural producers and shippers on various modes of transportation, such as the weekly Grain Transportation Report, the Refrigerated Transport Quarterly, quarterly issues of the Ocean Rate Bulletin and Agricultural Container Indicators, and the semiannual Agricultural Ocean Transportation Trends.

Our transportation specialists are called upon to provide information and advice when agricultural transportation is disrupted, such as late in 2002, when a labor stoppage closed the West Coast ports and threatened millions of dollars of losses for agriculture from commodities spoiled in transit. After 9/11, we are increasingly asked to provide more analyses on transportation security for agricultural products. In 2003, AMS developed a Transportation Security Briefing Book using the information currently available. The book provides an overview of the agricultural transportation system, existing safety measures, and discusses the adverse effects of past disruptions in the system. While this is a good start, we have found that much more study is needed in this area for all modes of transport, but particularly for trucking, which moves 90 percent of agricultural freight for at least one segment of its transportation to destination.

Finally, AMS works in close cooperation with both the Food and Nutrition Service (FNS) and the Farm Services Administration (FSA) to administer USDA's nutrition assistance and surplus commodity programs. AMS purchases agricultural commodities under authority of Section 32 of the Act of August 24, 1935, which permanently authorized an appropriation equal to 30 percent of customs receipts to encourage the exportation and domestic consumption of agricultural commodities. These funds, plus unused balances up to $500 million from the previous fiscal year, may be authorized by the Secretary to support markets by purchasing commodities in temporary surplus, for domestic nutrition assistance programs, for diversion payments and direct payments to producers, for export support, and disaster relief.

AMS retains only about 13 percent of the funds appropriated under Section 32. In 2005, AMS expects to retain $800 million, half of which—$400 million—will be spent on purchases for the Child Nutrition Programs. Most of the rest is available to AMS' commodity purchases program for emergency surplus removal. Eighty-six percent of the $6.2 billion total appropriation will be transferred to FNS to administer the Child Nutrition Programs and 1 percent to the Department of Commerce to develop fishery products.

The commodities purchased by AMS are donated to various nutrition assistance programs such as the National School Lunch Program, the Emergency Food Assistance Program, and the Food Distribution Program on Indian Reservations, according to their needs and preferences. In fiscal year 2003, AMS purchased 1.46 billion pounds of commodities that were distributed by FNS through its nutrition assistance programs.

AMS purchases the non-price supported commodities—meat, fish, poultry, egg, fruit and vegetable products—and FSA supplies the price-supported commodities—flours, grains, peanut products, cheese and other dairy products, oils and

shortenings—that supply the National School Lunch Program and other nutrition assistance programs administered by FNS.

To maximize the efficiency of food purchase and distribution operations, AMS, FNS, and FSA each provide a component of program administration according to their organizational structure and expertise, but the system is complex and requires close coordination. AMS and FSA purchase for FNS the entitlement commodities provided to schools. Schools and other nutrition assistance programs can also receive bonus commodities that are purchased to support agricultural markets through AMS' surplus commodity program. AMS and FSA are responsible for issuing and accepting bids, and awarding and administering contracts. FNS is responsible for taking commodity orders from the States, monitoring purchases and entitlements throughout the year, and the overall administration of the commodity nutrition assistance programs. Before a purchase is announced, AMS and FSA specialists work with potential vendors, FNS, and food safety officials to develop a specification for each product purchased that details product formulation, manufacturing, packaging, sampling, testing, and quality assurance. After market conditions, availability, and anticipated prices are assessed, and recipient preferences determined, AMS and FSA invite bids for particular U.S. produced and domestic origin food products under a formally advertised competitive bid program. Bids received from responsible vendors are analyzed and contracts are awarded by AMS and FSA. FSA administers the payments to vendors, ensures the proper storage of commodities when needed, and assists in their distribution.

To better coordinate the operations between the three agencies and control the vast array of details inherent to the procurement process, the Processed Commodities Inventory Management System, or PCIMS, was developed more than 10 years ago to track bids, orders, purchases, payments, inventories, and deliveries of approximately $2.5 billion of commodities used in all domestic and foreign food assistance programs every year and another $1 billion in price support commodity products maintained in inventory. PCIMS is still being used by the three agencies with modifications having been made over the years, when feasible, to add capabilities such as financial tracking or to meet changes in program delivery.

FISCAL YEAR 2005 BUDGET REQUEST

This leads us to the first of our two budget requests for fiscal year 2005, which involves both a multi-agency partnership and an electronic (e-) government initiative that will significantly improve customer service.

WEB-BASED SUPPLY CHAIN MANAGEMENT SYSTEM

AMS, FNS and FSA are working together to replace PCIMS with a Web-Based Supply Chain Management System, or WBSCM. For fiscal year 2005, AMS is requesting funding of $10 million in our Marketing Services appropriated account to begin developing the entire new system rather than each of the three agencies separately requesting portions of the funding needed.

WBSCM has undergone extensive reviews within USDA and was approved as one of the Department's selected e-government "smart choice" initiatives. WBSCM is designed to greatly reduce the time required for processing purchases; shorten delivery times; improve USDA's ability to collaborate with other Departments; improve reporting capability; reduce transportation, inventory, and warehousing costs; and enable future system updates as needed. Furthermore, the system will create a singe point of access for customers, allow us to share information more quickly and conveniently, automate internal processes, and assist in breaking down bureaucratic divisions. Eventually, WBSCM will be able to support agencies that manage similar commodity distribution programs for export. The Foreign Agricultural Service, the Agency for International Development, and the Maritime Administration, have been included in the development phases to ensure the new system can address the needs of export programs.

Over the last few years AMS, FNS, and FSA have undertaken extensive business practice reengineering efforts. Since PCIMS was developed and "hard coded" to automate the business practices of the time, it often cannot be modified to accept significant changes in process without undue costs. As a result, agency employees frequently have to develop electronic entries external to PCIMS and then update the system with the results. In contrast, WBSCM is designed to use commercial off the shelf software which will speed up implementation, incorporate industry and commercial best business practices, and give the agencies the flexibility to reconfigure the system after implementation when processes change. We expect that increased efficiency, better coordination, and improved services will begin as soon as the basic system is in place in mid-fiscal year 2007, when WBSCM will provide those services

being performed by PCIMS. Until then, we must continue to maintain the PCIMS system.

AGRICULTURAL TRANSPORTATION SECURITY

Our second proposal this year is to strengthen our agricultural transportation security expertise within the Transportation Services program. We are requesting $300,000 to produce more in-depth analyses of agricultural transportation security. Transportation is a critical link in the food supply chain. Closer analysis of the sector will provide the information needed for critical assessments of the strengths and vulnerabilities of the various transportation modes used to move farm inputs, food, and other agricultural products from farm to market. These funds will strengthen USDA's Homeland Security efforts by helping to safeguard the U.S. food supply and supporting the Department of Homeland Security. We will be better able to provide the information requested by policy officials in planning strategies to prevent potential disruptions, and to provide comprehensive information more quickly when any emergencies occur. Our current expertise and established contacts with transportation providers give us a distinct advantage in addressing agricultural transportation security issues. The transportation industry also has a serious interest in protecting shipments. For example, the Agricultural and Food Transporters Conference (AFTC) recently requested help from AMS in developing voluntary security guidelines. AMS is supporting a cooperative effort between USDA and the AFTC to prepare a guidebook. With expanded information and analysis, we will also be better able to advise agricultural producers and shippers on improving their own security.

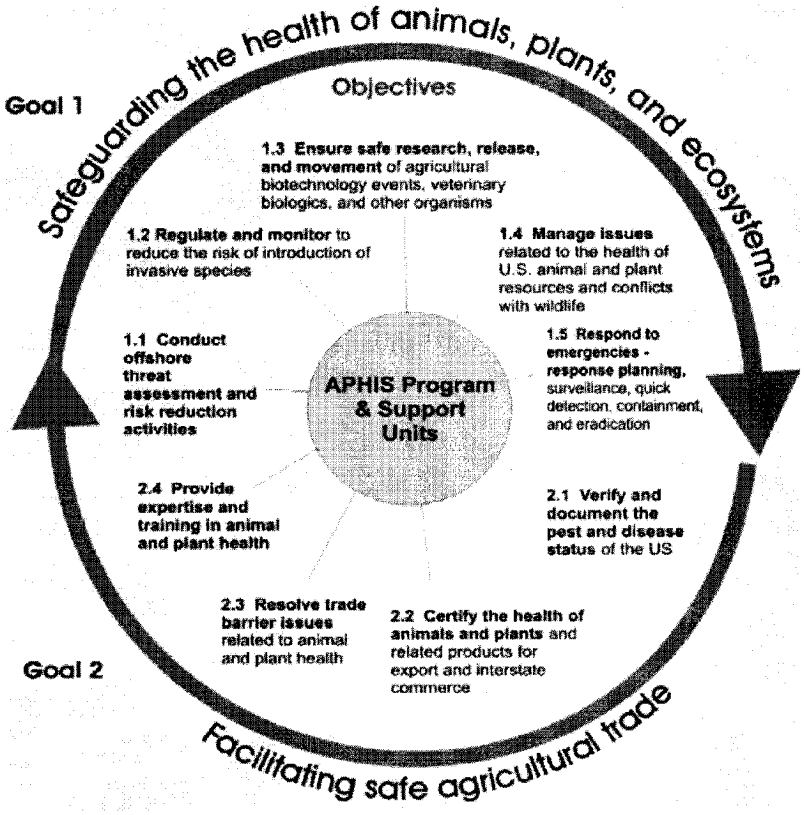
BUDGET REQUEST SUMMARY

Our total budget request includes $86 million for Marketing Services, which includes an increase for pay costs partially offset by a decrease for savings associated with information technology. We also include a decrease of $2 million in Federal-State Marketing Improvement Program grants funding under Payments to States and Possessions. These funds were provided in fiscal year 2004 to support Wisconsin specialty products. We request $11 million in Section 32 Administrative funds for commodity purchasing and $16 million for Marketing Agreements and Orders. These requests also include an increase for pay costs. Thank you for this opportunity to present our budget proposal.

PREPARED STATEMENT OF DR. PETER FERNANDEZ, ACTING ADMINISTRATOR, ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Mr. Chairman and members of the Subcommittee, it is indeed a pleasure for me to represent the Animal and Plant Health Inspection Service (APHIS) before you today. APHIS is an action-oriented agency that works with other Federal agencies, Congress, States, agricultural interests, and the general public to carry out its mission to protect the health and value of American agriculture and natural resources. APHIS strives to assure its customers and stakeholders that it is on guard against the introduction or reemergence of animal and plant pests and diseases that could limit production and damage export markets. At the same time, APHIS monitors for and responds to potential acts of agricultural bioterrorism, invasive species, diseases of wildlife and livestock, and conflicts between humans and wildlife. APHIS also addresses sanitary and phytosanitary trade barriers and certain issues relating to the humane treatment of animals. Finally, APHIS ensures that biotechnology-derived agricultural products are safe for release in the environment. We have developed a strategic plan to help us accomplish these objectives, and I would like to report on our fiscal year 2003 protection efforts and our fiscal year 2005 budget request in that context.

APHIS' Protection System



APHIS' protection system is based on a strategic premise that safeguarding the health of animals, plants, and ecosystems makes possible safe agricultural trade and reduces losses to agricultural and natural resources. All nine objectives in the protection system are key components of this strategic premise. Failing to succeed in any one objective will eventually lead to overall failure, and American farmers will not reach their potential export markets. Additionally, the protection system is a key component of USDA's Homeland Security role. The United States has a vital stake in the health of American agriculture, both economically and in terms of feeding our people and many throughout the world. Terrorists could well recognize that vital stake and seek to attack it.

Five Objectives for Safeguarding Health of Animals, Plants, and Ecosystems

Objective 1.1—Conduct offshore threat assessment and risk reduction activities.—In this era of increasing globalization and advancing technologies, APHIS must constantly assess the exotic health threats approaching our borders, and engage in offshore pest or disease eradication activities when the threat is imminent and the potential impact severe.

To prevent the introduction of costly foreign animal diseases into the United States, our Foreign Animal Diseases (FAD) and Foot-and-Mouth Disease (FMD) program works to detect and control outbreaks of animal diseases in foreign countries far from our shores. This is our first line of defense against foreign animal diseases and has become more significant as international trade and travel have increased. APHIS conducts operations overseas through bilateral agreements and works with multilateral organizations, such as the World Organization for Animal Health (OIE).

Last year, for example, through an agreement with Panama and Mexico, we collected 1,260 samples of suspected vesicular disease throughout Central America from field investigations and tested the samples in Panama. Fortunately, all tested negative for FMD, while 639 were diagnosed as vesicular stomatitis.

Through our Fruit Fly Exclusion and Detection program, we cooperate with the Governments of Mexico, Guatemala, and Belize on the Moscamed program to eradicate and control the Mediterranean Fruity Fly (Medfly), which could cause $2 billion in losses if it became established in the United States. Moscamed's current top priorities are to eradicate the Medfly from Chiapas, Mexico, and move the barrier south into Guatemala in an effort to achieve APHIS' and its cooperators' goal of eradicating Medfly from Central America and thereby providing more secure prevention against the threat Medfly poses to the United States. A major component of the program is the production and release of sterile flies to disrupt normal reproduction. In fiscal year 2003, the Central America Medfly program produced 2.2 billion sterile fruit flies a week, exceeding its goal of producing 2 billion per week. This production increase allowed more flies to go to the preventive release program in the United States.

Through our Tropical Bont Tick program, APHIS employees are preventing the introduction of heartwater and other diseases transmitted by tropical bont ticks into the livestock industry and wildlife populations of the United States from affected Caribbean islands. The cooperative program has eradicated ticks from six of the nine islands involved so far, bringing us closer to our goal of eradicating this pest from the Western Hemisphere.

Objective 1.2—Regulate and monitor to reduce the risk of introduction of invasive species.—APHIS regulates the import of agricultural products, including commercial shipments and items carried into the United States by travelers, to prevent the entry of foreign pests and diseases. We work closely with the Department of Homeland Security (DHS) to monitor and intercept items that arrive at ports of entry.

In fiscal year 2003, APHIS and DHS agricultural employees inspected the baggage of nearly 74 million arriving passengers. Passenger baggage is inspected manually, with x-ray technology, or through the use of detector dogs. Agricultural inspectors also cleared 54,033 ships and 3,128,660 cargo shipments. In cooperation with DHS, we increased the number of cargo inspections by 43 percent over fiscal year 2002 because of the high entry risk of exotic wood boring and bark beetles, like Asian long-horned beetle and emerald ash borer. In total, agricultural inspectors intercepted 82,631 reportable pests at land borders, maritime ports, airports, and post offices. At plant inspection stations, our inspectors cleared 176,761 shipments containing over 1.2 billion plants units (cuttings, whole plants, or other propagative materials) and intercepted 4,260 pests.

Part of APHIS' safeguarding strategy is to prevent the intentional introduction of illegal products through market surveys, investigations, and enforcement action. In fiscal year 2003, our Safeguarding, Intervention, and Trade Compliance (SITC) staff and field personnel seized 15,706 illegal plant products and 488 illegal meat, poultry, and dairy products and found 112 reportable pests. When SITC detects a prohibited item, we identify the item's origin and the responsible shippers, importers, and broker. By maintaining the relevant information in databases, the program can target specific commodities and importers. This year, SITC investigations led to the detection of 82 violations at markets and distributors' warehouses.

APHIS' Animal and Plant Health Regulatory Enforcement program conducts regulatory enforcement activities to prevent the spread of animal and plant pests and diseases in interstate trade. These activities include inspection, surveillance, animal identification, and prosecution. This year, APHIS continued the development of a multi-year project to improve a headquarters-based, on-line computer system to track investigations and automate the enforcement process. The database will help our enforcement efforts by allowing APHIS programs and other agencies such as the Departments of Homeland Security and Treasury to share critical information and identify individuals, companies, cargoes, carriers, or pathways posing risk.

In fiscal year 2003, APHIS conducted 1,782 investigations involving plant quarantine violations resulting in 142 warnings, 682 civil penalty stipulations, seven Administrative Law Judge decisions, and approximately $1 million in fines. Regarding animal health programs, we conducted 1,425 investigations, resulting in 210 warnings, 39 civil penalty stipulations, five Administrative Law Judge decisions, and approximately $44,900 in fines. Also during fiscal year 2003, the program conducted 76 investigations of alleged Swine Health Protection Act violations in Puerto Rico. This was slightly less than the target of 80 investigations, mostly due to providing support for the exotic Newcastle disease outbreak in California.

Objective 1.3—Ensure safe research, release, and movement of agricultural biotechnology events, veterinary biologics, and other organisms.—The growth of agricul-

tural biotechnology hinges on the public's acceptance of this technology as safe, and APHIS' regulatory role is key to ensuring global acceptance. In addition to agricultural biotechnology, the Agency monitors and regulates to ensure safe agricultural research and commercialization activities involving the movement of non-indigenous organisms and veterinary biologics.

APHIS' Biotechnology Regulatory Services (BRS) program, created in August 2002, regulates the introduction (importation, interstate movement, and field release) of genetically engineered organisms such as plants, insects, microorganisms and any other organism that is known to, or could be, a pest. APHIS also has determined that BRS may potentially regulate animals, insects, and other disease agents relevant to livestock health. Through a strong regulatory framework, BRS determines the conditions under which genetically engineered organisms can be introduced into the United States and allows for the importation, interstate movement, and field release of these materials only after rigorous conditions and safeguards are put into place. Under the authority of the Plant Protection Act of 2000, APHIS can pursue penalties for failure to adhere to our regulations, permit conditions, and requirements.

With the creation of our new biotechnology compliance program, we have chosen measures that will accurately and visibly reflect the effectiveness of our inspection efforts for the testing of products that carry a higher degree of perceived risk. We believe that increased frequency of inspections—especially at high risk sites—coupled with efforts to improve the quality of inspections through expanded training, will translate into a high degree of stakeholder and public confidence that these products will be safely confined and not inadvertently enter the food supply. Our performance target for fiscal year 2004 is to inspect 10 percent of low risk sites, 40 percent of medium risk sites at least once during the growing season, and 100 percent of pharmaceutical and industrial sites a total of seven times—five times during the growing season and two times afterwards.

Our Veterinary Biologics program continues to ensure that veterinary biologics products are pure, safe, potent, and effective. Our goal is to ensure the availability of quality veterinary biological products for the diagnosis, prevention, and treatment of animal diseases. The program will continue to respond to emerging diseases with expedited reviews and inspections for new veterinary biologics, and it will follow a risk-based approach to inspect and test other products.

In fiscal year 2003, APHIS performed 78 regulatory actions following routine inspections and 24 investigations of possible regulation violations. APHIS' Center for Veterinary Biologics found the marketing of unlicensed veterinary biologics and false or misleading advertising of licensed veterinary biologics in over half of these investigations. Through education, cooperation, and regulatory actions, APHIS helped industry achieve increased compliance with the Virus-Serum-Toxin Act.

Objective 1.4—Manage issues related to the health of U.S. animal and plant resources and conflicts with wildlife. Agricultural stakeholders also expect APHIS to help solve many types of health-related production issues in the United States. For example, producers need help in dealing with area-wide wildlife damage control problems. Indigenous pest problems affecting multiple States, such as boll weevil and grasshoppers, also require APHIS' attention. We are not alone in these efforts and have good relationships are with our State and Tribal partners in conducting these eradication and control programs. That cooperation, in addition to support from academia and industry, is essential for these types of programs to succeed.

We continue to make progress on a number of other animal health programs as well. At the beginning of fiscal year 2003, there was one pseudorabies-quarantined premise in the United States, compared to 12 at the beginning of fiscal year 2002. By the end of fiscal year 2003, there were no swine commercial production premises under quarantine for pseudorabies. As of September 30, 2003, there were 1,776 flocks participating in the Scrapie Flock Certification Program of which 105 are certified, 1,663 are completely monitored, and 8 are selective monitored flocks. This is in comparison to 1,539 flocks enrolled, 78 flocks certified, 1,452 flocks completely monitored, and 9 flocks selectively monitored as of September 30, 2002. To continually improve on the 46 States, Puerto Rico, and the Virgin Islands as accredited Tuberculosis-free, the program depopulated three dairy herds in California, four beef herds in Michigan, and one beef herd in Texas during fiscal year 2003.

Among a number of protection efforts, APHIS' Wildlife Services (WS) Operations program works to protect agricultural crops from wildlife damage, to protect livestock from predation, and to protect human safety by preventing wildlife collisions with aircraft. In fiscal year 2003, the Agency's beaver damage management activities in several States averted $25 million in impending damage to forest and agricultural resources, waterways and highway infrastructures. As wolf populations continue to increase, so do requests for assistance with wolf predation. As a result,

APHIS responded to 179 requests for assistance with wolf predation on livestock or domestic dogs during fiscal year 2003 in Minnesota alone. In the west, APHIS responded to 41 requests for assistance with gray wolf predation in Idaho and 87 requests in Montana. Airports reported approximately 6,100 wildlife strikes to civil aircraft in 2002, with the U.S. Air Force alone reporting more than 3,800 strikes to military aircraft. Wildlife strikes cost civil aviation in the United States over $480 million in damages in 2002. The requests for APHIS assistance in managing wildlife hazards at airports and military air bases continue to increase. In fiscal year 2003, APHIS wildlife biologists provided wildlife hazard management assistance to over 500 airports nationwide for the protection of human safety and property, compared to only 42 airports in fiscal year 1990 and 409 airports in fiscal year 2002. At JFK International Airport, APHIS biologists have reduced gull strikes by over 80 percent in 2000–2003 compared to strike levels in the early 1990s.

APHIS' Wildlife Services (WS) Methods Development program, through the National Wildlife Research Center (NWRC), functions as the research arm of APHIS' Wildlife Services program by providing scientific information for the development and implementation of effective, practical, and socially acceptable methods for wildlife damage management. This helps ensure that high-quality technical and scientific information on wildlife damage management is available for the protection of crops, livestock, natural resources, property, and public health and safety. The program provides technical support for the development of 5 drug/vaccine products through Investigational New Animal Drug Authorizations under the Food and Drug Administration. These materials are under development as wildlife immobilizing agents and contraceptive products. APHIS continued to develop and evaluate nonlethal methods for managing blackbird damage to sunflowers and rice by conducting extensive laboratory testing of registered chemicals for bird repellency characteristics. Scientists continued multi-year research studies at various airports in the United States to reduce wildlife strike hazards. These scientists researched turf management, non-lethal repellents, and dispersal techniques to minimize strikes by gulls, waterfowl, turkey vultures, hawks, and other species that threaten aviation safety. In fiscal year 2003, we met our performance target of testing and/or improving 18 wildlife damage management methods and will maintain this target for fiscal year 2004.

APHIS' Animal Welfare program carries out activities designed to ensure the humane care and handling of animals used in research, exhibition, the wholesale pet trade, or transported in commerce. The program places primary emphasis on voluntary compliance through education with secondary emphasis on inspection of facilities, records, investigation of complaints, reinspection of problem facilities, and training of inspectors. However, when necessary, APHIS personnel investigate alleged violations of Federal animal welfare and horse protection laws and regulations and oversee and coordinate subsequent prosecution of violators through appropriate civil or criminal procedures. In fiscal year 2003, we conducted 365 animal welfare investigations resulting in 172 formal cases submitted for civil administrative action. We also issued 90 letters of warning and resolved 44 cases with civil penalty stipulations resulting in $56,373 in fines. Administrative Law Judge Decisions resolved another 58 cases resulting in $668,995 in fines.

Objective 1.5—Respond to emergencies—response planning, surveillance, quick detection, containment, and eradication.—Even though we devote many resources to pest and disease prevention and regulatory compliance to safeguard agricultural health, it is impossible to intercept every potential biological threat. APHIS must have the capacity to quickly respond in order to limit the spread of the outbreak and to eradicate it so that production losses are minimized and exports of affected commodities do not suffer long-term disruptions.

APHIS' Emergency Management System (EMS) is a joint Federal-State-industry effort to improve the ability of the United States to deal successfully with animal health emergencies, ranging from natural disasters to introductions of foreign animal diseases. The EMS program identifies national infrastructure needs for anticipating, preventing, mitigating, responding to, and recovering from such emergencies. By Presidential Homeland Security Directive, APHIS is restructuring its emergency response systems according to the National Incident Management System, or NIMS. APHIS implemented the incident command structure in response to the exotic Newcastle disease (END) outbreak in California, Arizona, Nevada, and Texas during fiscal year 2003. During the END outbreak, APHIS followed the NIMS structure and established five incident command posts in three States.

This same structure was put into place when, on December 23, 2003, laboratory testing at the National Veterinary Services Laboratories indicated that a single cow, slaughtered on December 9, 2003, in Washington State, tested positive for BSE. The world reference laboratory in the United Kingdom confirmed these presumptive

positive results on December 25 for BSE, and we immediately began a swift and comprehensive investigation.

The epidemiological tracing and DNA evidence proved that the BSE positive cow was born on a dairy farm in Alberta, Canada in 1997. She was moved to the United States in September 2001 along with 80 other cattle from that dairy. The epidemiological investigation to find additional animals from the source herd led to a total of 189 trace-out investigations. These investigations resulted in complete herd inventories on 51 premises in three States: Washington, Oregon and Idaho.

On February 9, 2004, APHIS announced that we had completed our field investigation of the BSE case in Washington. During our investigation, a total of 255 "Animals of Interest"—animals that were or could have been from the source herd—were identified on 10 premises in Washington, Oregon and Idaho. All 255 animals were depopulated and sampled for BSE testing. Results were negative on all samples. The carcasses from all of the euthanized animals were properly disposed of in accordance with all Federal, State, and local regulations. Consistent with international guidelines on BSE, we focused on tracing the 25 animals born into the birth herd of the index cow during a 2-year window around her birth. Based on normal culling practices of local dairies, we estimated that we would be able to locate approximately 11 of these animals. In fact, APHIS definitively located 14 of these animals.

We are confident that the remaining animals represent very little risk. Even in countries like the United Kingdom where the prevalence of BSE has been very high, it has been very uncommon to find more than one or maybe two positive animals within a herd.

Thus far in fiscal year 2004, USDA has transferred $80.4 million from the Commodity Credit Corporation (CCC) to APHIS for BSE-related activities. APHIS is using these funds to respond to the Washington State incident and to enhance BSE surveillance around the country. This CCC funding will supplement the funds already set aside for BSE surveillance in APHIS' base appropriation. This enhanced surveillance plan incorporates recommendations from the international scientific review panel and the Harvard Center for Risk Analysis; both have reviewed and supported the plan.

On December 30, 2003, Secretary Veneman announced that an international panel of experts would be convened to review our BSE investigative efforts and recommend enhancements to our BSE program. The panel delivered their report on February 4, 2004, and commended USDA for conducting such a comprehensive epidemiological investigation. The panel also made recommendations for further enhancements to the BSE program. The Secretary applied all of this information in considering future actions with regard to BSE, and on March 15, she announced a plan to enhance the BSE surveillance program. Previous targeted surveillance efforts were designed to detect BSE in the adult cattle population at the level of at least one infected animal per million adult cattle with a 95 percent confidence level. The goal of the new plan is to test as many cattle in the targeted high-risk population as possible in 12 to 18 months, and then evaluate future actions based on the results of this effort.

The plan also incorporates random sampling of apparently normal, aged animals at slaughter. More than 86 percent of all adult cattle processed annually are slaughtered in 40 plants; random sampling efforts will be focused on these plants.

More intensive surveillance will allow us to refine our estimates of the level of disease present in the U.S. cattle population and provide consumers, trading partners, and industry better assurances about our BSE status. Testing will be conducted at USDA's National Veterinary Services Laboratories and at participating network contract laboratories. As an example, if a total of at least 268,444 samples is collected from the targeted population, we believe this level of sampling would allow USDA to detect BSE at a rate of 1 positive in 10 million adult cattle (or 5 positives in the entire country with a 99 percent confidence level). We also plan on testing at least 20,000 BSE slaughter samples from apparently healthy, aged bulls and cows. During this effort, we will be utilizing approved rapid screening tests, working with industry on disposal issues, and enhancing our BSE education and outreach activities.

USDA remains confident in the safety of the U.S. beef supply. Out of an abundance of caution, USDA recalled all meat products processed in the affected slaughter plant the same day as the positive cow. However, the meat presents an extremely low risk to consumers, because all of the central nervous system related tissues—those most likely to contain the BSE agent—were removed from the affected animal during slaughter and did not enter the human food supply.

Even with the recent detection, the United States continues to have a very low BSE risk. An independent assessment conducted by Harvard University in 2001 and

again in 2003 demonstrated that even with a detection of BSE in this country, United States control efforts would minimize any possible spread of the disease and ultimately eliminate it from the U.S. cattle population. These controls include a long-standing ban on imports of live cattle, other ruminants, and most ruminant products from high risk countries; the Food and Drug Administration's 1997 prohibition on the use of most mammalian protein in cattle feed; and an aggressive surveillance program that has been in place for more than a decade. In each of the past 2 years, the United States tested over 20,000 head of cattle for BSE, which is 47 times the recommended international standard.

We opened the APHIS Emergency Operations Center (AEOC) in March 2003. The AEOC is a state-of-the-art facility that allows a national management response team to communicate with field personnel and USDA leadership during an outbreak situation. Communications capabilities include video teleconferencing, advanced computer interfaces, geographical information system mapping, and a strong multimedia component.

Through the Pest Detection program, APHIS and its State cooperators work to ensure the early detection of harmful or invasive plant pests and weeds through the Cooperative Agricultural Pests Survey (CAPS) program. The CAPS program provides the domestic infrastructure necessary to conduct national surveys for plant pests and weeds and document the results in a national database, the National Agricultural Pest Information System (NAPIS). NAPIS provides a summary of pest survey results and allows APHIS to track the spread of pests within the United States, demonstrate their presence or absence, plan their control, and support the export of agricultural commodities. APHIS is currently engaged in a multi-year effort to enhance its early detection program through an increased level of communication and cooperation with its State partners, increased staffing levels, the use of new technology, and a new focus on international pest risk analysis. These efforts will help us meet our goal of detecting significant pest introductions before a new pest can cause serious damage. Finding newly arrived exotic pests before they spread will reduce the money spent on costly eradication programs and prevent losses to farmers and our natural ecosystems.

APHIS has completed pest risk assessments for ten of the 18 pests on the national CAPS list for fiscal year 2003 and 2004 and is working with State cooperators to develop State CAPS lists. We are also instituting CAPS committees at the State, regional, and national levels to ensure that stakeholders are involved in the process of targeting pests for survey. In fiscal year 2003, APHIS and 21 States conducted the Exotic Wood-Borer and Bark Beetle Survey, one of our new commodity-or resource-based surveys. While the data is still not complete, this year's survey turned up evidence of three new forest pests previously not known to exist in the United States. We believe that these new pests provide strong evidence of the need for the nationally directed and risk-based detection program that we are currently implementing.

APHIS' Animal Health Monitoring and Surveillance program continues to conduct activities such as: monitoring and surveillance of various animal disease programs, foreign animal disease surveillance and detection, emergency disease preparedness and response, animal health monitoring, and epidemilologic support and delivery for both ongoing disease programs and post-disease eradication programs. For example, APHIS completed the Scrapie Ovine Slaughter Surveillance project sample collection by gathering 12,508 samples from 22 slaughter plants and one slaughter market. Losses from affected flocks cost producers approximately $20 to $25 million annually.

APHIS has been challenged with numerous emergencies over the last several years. However, we took quick and aggressive action to address the following plant and animal situations: Asian Longhorned Beetle, Chronic Wasting Disease, Citrus Canker, Emerald Ash Borer, Exotic Newcastle Disease, Karnal Bunt, Mediterranean Fruit Fly, Mexican Fruit Fly, Pierce's Disease/Glassy-winged Sharpshooter, Rabies, Spring Viremia of Carp, and Tuberculosis. The Secretary used her authority to transfer over $378 million to battle these pests and diseases. Without the quick detection and early, rapid response, the cost to control these outbreaks would have undoubtedly been higher.

Four Objectives for Facilitating Safe Agricultural Trade

APHIS' two goals of safeguarding U.S. agriculture and facilitating international agricultural trade reinforce each other. By protecting and documenting the health of our agricultural products, we can retain existing markets and open new markets for our farmers. By facilitating safe trade with other countries (including activities such as monitoring world agricultural health and helping developing countries build

regulatory capacity), we help ensure that imported products will not threaten our domestic production capability and health status.

Objective 2.1—Verify and document the pest and disease status of U.S. agriculture and related ecosystems.—The World Trade Organization's (WTO) Sanitary and Phytosanitary (SPS) Agreement and the North American Free Trade Agreement commit countries to recognizing disease- and pest-free areas within a country even if a particular pest or disease exists elsewhere in the nation. This concept of regionalization has resulted in APHIS' becoming increasingly involved in demonstrating our pest and disease free status to allow agricultural exports to trading partners.

APHIS' Pest Detection program conducted 150 surveys to document the pest status of our plant resources and support U.S. producers' ability to export their products. For example, by collecting extensive survey data demonstrating the limited distribution of Karnal bunt in the United States, APHIS provides assurance to our trading partners that the disease is not present in major wheat-producing areas of the United States, thereby ensuring annual agricultural exports of up to $5 billion and supplying the raw ingredients for domestic and foreign customers of flour, pasta, and other wheat products. Plum pox is another case in which the collection of national data has helped to keep budwood markets open by demonstrating the absence of the pest from various areas around the United States.

APHIS officials collaborate with State and other Federal agencies to conduct animal health surveillance activities through the Animal Health Monitoring and Surveillance (AHMS) program. These activities include pre- and post-entry testing of imported animals, sample collection at slaughter, and routine testing of animals for export and interstate movement. APHIS also conducts surveillance for domestic animal disease eradication programs, like brucellosis, tuberculosis, chronic wasting disease, and others. This surveillance information allows APHIS to make key regulatory decisions. In doing so, APHIS strives to preserve U.S. exports markets, protect livestock or poultry producers in disease-free areas, and provide the best options possible for those producers who are affected by our regulatory decisions.

When foreign animal disease outbreaks occur in the United States, our trading partners routinely ban U.S. animal and animal product exports until APHIS has the opportunity to confirm the extent of the disease's spread and demonstrate what regulatory actions are being taken to contain it. Last year, the poultry breeding and hatchery industry lost approximately $1 million per week due to bans by various trading partners on U.S. poultry exports because of exotic Newcastle disease. Our trading partners will lift such bans in unaffected and unregulated areas only if we can convince them that measures are being taken to mitigate the risk of the disease's spread via host commodity exports. Providing our trading partners accurate and detailed information about a foreign animal disease outbreak and the subsequent Federal/State disease management response is critical. This information gives our trading partners the assurances they need without exposing them to undue risk. Such a regionalized approach helps minimize trade disruption and negative market reactions.

Objective 2.2—Certify the health of animals and plants and related products for export and interstate commerce.—In carrying out this role, APHIS spends well over $100 million on disease diagnostics and epidemiology and pest detection infrastructure. This infrastructure makes our health certificates credible for trading partners, but it also is instrumental for quickly detecting and limiting the spread of outbreaks of new pests and diseases, part of our emergency response strategy (Objective 1.5).

The Import/Export program promotes simple, science-based export conditions and negotiates requirements based on technical-level mitigation and guidelines established by OIE. The program is working hard to strengthen its evaluation and risk assessment capabilities to meet international and domestic responsibilities and respond to international and domestic requests for regionalization in a timely manner. For example, during fiscal year 2003 the Import/Export program increased its capacity to conduct regionalization analyses for foreign markets (import purposes) and domestic markets (export purposes). During the early stages of the exotic Newcastle disease outbreak in fiscal year 2003, many countries—including all members of the European Union—suspended poultry imports from all regions of the United States. APHIS, however, identified END-free regions of the country and helped these regions regain market access. These actions helped protect the entire U.S. poultry export industry, which has an estimated annual worth of $2.5 billion.

APHIS' Agricultural Quarantine Inspection program facilitates the export of agriculture shipments through EXCERT, an electronic database containing plant health import requirements for over 200 countries. APHIS export certifications ensure that U.S. products meet the agricultural requirements of the country of destination. In fiscal year 2003, APHIS issued over 400,000 Federal plant health export certificates

for agriculture shipments, including the issuance of heat treatment certificates for coniferous solid wood packing materials to the People's Republic of China.

Objective 2.3—Resolve trade barrier issues related to animal and plant health.—Because of APHIS' expertise in animal and plant health issues and our regulatory role (Objective 1.2), the Agency serves as a key resource for trade policy agencies, like the Foreign Agricultural Service and the U.S. Trade Representative, in resolving sanitary and phytosanitary issues that often become trade barriers (Objective 2.3). The negotiations that occur to resolve these issues often result in trading partners providing additional information about the pests or diseases in question, and this information in turn leads to more effective preventive regulatory strategies.

Officials with the Trade Issue Resolution and Management program work to minimize trade disruptions caused by animal and plant health issues. In fiscal year 2003, APHIS retained poultry markets in Japan, Korea, and the Philippines worth over $169 million, expanded market access for apples in Mexico worth $88 million, and opened new markets for seed potatoes to Uruguay and apricots from the Pacific Northwest to Mexico. Additionally, APHIS expanded market access for U.S. cherries, canola seed, and potatoes in Mexico, and with the concerted efforts of APHIS, Foreign Agricultural Service, and the Office of the United States Trade Representative, we retained markets for wheat in Argentina and Peru.

When individual agricultural shipments are held up at foreign ports, APHIS attachés correct problems and negotiate with host government officials to facilitate the shipment's acceptance. APHIS obtained authorization for apples at four additional ports of entry in Mexico resulting in the release of a $5 million apple shipment. In addition, APHIS facilitated $1 million worth of U.S. cotton in Chile, three rice shipments in Costa Rica and Guatemala, the release of $13 million in citrus shipments held by Japanese officials, and the waiving of phytosanitary certification with Romanian officials for soy beans, allowing a shipment of 14,000 tons of soybeans valued at over $3 million.

Objective 2.4—Provide expertise and training in animal and plant health.—The WTO's SPS Agreement requires member countries to provide technical assistance to developing countries to enable those countries to participate more fully in the global trade arena. Using cooperative agreements, preclearance trust fund agreements, and other international arrangements, APHIS provides many countries with technical assistance to strengthen their animal and plant health infrastructure, risk assessment capacity, and food production capabilities (Objective 2.4). By doing this, APHIS not only fulfills requirements for the SPS Agreement but also improves offshore threat assessment and risk reduction capabilities (Objective 1.1).

APHIS attachés continue to identify specific weaknesses in foreign regulatory systems and provide technical assistance where appropriate. Capacity building improves foreign countries' regulatory infrastructure, U.S. relationships with key foreign officials, United States regulatory concepts and approaches, and, ultimately, the agricultural health status of the foreign country.

In fiscal year 2003, the Veterinary Biologics program continued working with the Committee of the Americas for the Harmonization for Registration and Control of Veterinary Medicines (CAMEVET). The objectives of this committee include coordinating technical information for the registration and control of veterinary medicines. The intention of this program is to exchange information and harmonizes technical procedures to improve the quality of veterinary medicines and the trade of products among countries in the Americas.

A part of APHIS' Veterinary Diagnostics program assists foreign governments in the diagnosis of animal diseases by maintaining national and international laboratory recognition with the highest quality reference assistance and by conducting developmental projects for rapidly advancing technologies. In fiscal year 2003, as an OIE reference laboratory, APHIS' National Veterinary Services Laboratories (NVSL) continued to use their diagnostic expertise to provide training, consultation, and assistance to both domestic and international laboratories. NVSL prioritized the evaluation/validation of new technologies such as the exotic Newcastle disease and Avian Influenza polymerase chain reaction and Chronic Wasting Disease kits to offer new tools for control of certain key diseases. NVSL also shipped 117,095 vials of reagents to domestic and foreign customers to meet critical testing needs. And, NVSL acquired a new chemistry analyzer for blood screening purposes and doubled the number of fraudulent cases detected over those detected in fiscal year 2002. The fraudulent blood testing program at NSVL helps to assure confidence in the health of animals exported from the United States to other countries.

NEW DIRECTION

After evaluating the current challenges and opportunities that exist today, APHIS has developed a new strategic plan of action that will set the Agency's course over the next 5 years. During this time, APHIS is committed to focusing on the following overarching goals: safeguarding the health of animals, plants, and ecosystems in the United States; facilitating safe agricultural trade; and ensuring effective and efficient management of programs to achieve its mission.

As part of its new strategic plan, APHIS intends to strengthen key components of its protection system by focusing on the following objectives:

—Ensuring the safe research, release, and movement of agricultural biotechnology;
—Strengthening the Agency's emergency preparedness and response;
—Resolving trade barriers related to sanitary and phytosanitary requirements;
—Reducing domestic threats through increased offshore threat-assessment and risk-reduction activities;
—Reducing the risk of invasive species introductions by enhancing risk-analysis capabilities; and,
—Managing issues related to the health of U.S. animal and plant resources and conflicts with wildlife.

FISCAL YEAR 2005 BUDGET REQUEST

APHIS has developed its fiscal year 2005 Budget Request in the context of the Strategic Plan, the overriding imperative of Homeland Security, and the need to restrain Federal spending. The fiscal year 2005 Budget Request for Salaries and Expenses under current law totals $828.4 million or $112 million more than the fiscal year 2004 Consolidated Appropriations Act. About $8.5 million is for the cost of the pay raise.

The fiscal year 2005 increase, approximately 15.5 percent above the fiscal year 2004 appropriation, is for initiatives designed to address the increasing threats to the health of American agriculture and Homeland Security and to support the President's Food and Agriculture Defense Initiative. About 40 percent of the increase, approximately $45.4 million, is an investment to substantially reduce the over $378 million fiscal year 2003 emergency transfers and to protect and expand the $53 billion annual agricultural export market by fully funding Federal costs up front in the budget. Other notable increases stem from the highest priority components of APHIS' Strategic Plan and the Food and Agriculture Defense Initiative. APHIS' request for fiscal year 2005 contains $94.36 million for programs that support the Food and Agriculture Defense Initiative, an increase of nearly $50 million over fiscal year 2004.

HIGHEST PRIORITY COMPONENTS OF THE STRATEGIC PLAN AND HOMELAND SECURITY

APHIS proposes to increase funding for the Biotechnology Regulatory Services program by $6.544 million. This will enable us to inspect all high risk fields five times during the growing season and two times in the subsequent season to provide the maximum confidence level that pharmaceutical and industrial developments are managed safely. Such a confidence level is necessary to convince skeptics and trading partners that these, and other biotechnologically derived products, are safe. That confidence is vital to the growth of the industry and American agriculture.

We propose to increase the Import-Export program by $3 million and the Pest Detection program by $1.5 million to fulfill APHIS' responsibilities under the Bioterrorism Preparedness and Response Act of 2002. APHIS must regulate possessors and users of "select agents," toxins and pathogens necessary for research and other beneficial purposes which could be deadly in the hands of terrorists.

In light of the first BSE case in the United States, we propose increasing the Animal Health Monitoring and Surveillance program by an additional $8.641 million to support enhanced BSE surveillance to maintain the confidence of the American people in the safety of the beef supply and allow us to continue our efforts to prevent the introduction and spread of BSE in the U.S. cattle population. In this program, we also request $33.197 million to accelerate implementation of a National Animal Identification program. Timely tracebacks of animals are integral to a rapid response and recovery to incursions of animal illness and foreign animal disease.

Early detection of new animal and plant pest or disease introductions has the potential to significantly reduce eradication costs and producer losses and, accordingly, is a high priority for APHIS. We propose to increase the funding available to our State cooperators through cooperative agreements for plant pest surveys and animal health monitoring efforts by $15.2 million (including $9.1 million for the Pest Detec-

tion program and $6.1 million for the Animal Health Monitoring and Surveillance program). In addition to requesting increased funding to provide to our cooperators, we are proposing a $6.202 million increase for the Pest Detection program to enhance our pest detection infrastructure and national coordination efforts. By establishing basic capacity in all 50 States now, we will enhance our ability to find and contain pests and diseases like citrus canker, Asian longhorned beetle, emerald ash borer, Karnal bunt, exotic Newcastle disease, and avian influenza before they become widespread and require expensive emergency eradication programs. Similarly, we request an increase in the Wildlife Services Operations program by $5 million to expand infrastructure to monitor and gather data on the disease status of free-ranging animals and integrate this data with existing agricultural animal health monitoring systems. APHIS will use this information to detect and respond to disease outbreaks in wildlife populations and mitigate the risk of wildlife diseases transmission to farmed livestock.

The budget requests a $5 million increase for the Biosurveillance program to enhance several data collection systems already in use, allowing us to improve our surveillance capabilities and establish connectivity with the integration and analysis function at DHS.

The increase of $3.149 million in the Trade Issue Resolution and Management program will allow APHIS to place more officials overseas to facilitate the entry of U.S. agricultural products and to help establish international standards based on sound science. Having APHIS attaches on site in foreign countries pays dividends weekly. They can intervene when foreign officials raise false barriers to the entry of individual American export shipments. In 2002, APHIS attachés successfully intervened to clear shipments worth $53 million in such cases.

We propose to increases the Low Pathogenic Avian Influenza (LPAI) program by $11.783 million to conduct a vigorous surveillance and control program in the live bird markets in the Northeast—the most threatening continuing reservoir of LPAI in the United States. Eliminating LPAI in these markets would help prevent costly eradication programs like the one we conducted in Virginia in 2002. It also would remove a barrier to poultry exports—a $2.2 billion market—that many countries have or are threatening to invoke. OIE is likely to upgrade LPAI status to "List A," which could result in more restrictions on our exports if we do not move to eradicate LPAI in the United States.

We also propose to increase the Foot and Mouth Disease/Foreign Animal Disease program by $4.229 million to further our goal of reducing domestic threats through increased offshore threat assessment and risk-reduction activities by placing more officers overseas to monitor animal disease incidence and assist foreign countries in controlling outbreaks. We propose to increase the Pest Detection program by $3.875 million to do the same for plant pests and diseases. We request an increase in the Tropical Bont Tick (TBT) program by $2.495 million to eradicate TBT from Antigua completely and quickly prevent threats to other islands already free, to control and eradicate TBT from St. Croix, and establish surveillance on other U.S. islands and mainland to determine if TBT has spread.

We propose to increase the Emergency Management Systems program by $10.625 million to enhance animal health emergency preparedness throughout the United States and to establish a vaccine bank to complement the North American Foot and Mouth Disease Vaccine Bank. This additional resource would include vaccines or preventives for other foreign animal disease of significance. These efforts will help protect our Nation's meat, poultry, and livestock exports, which are valued at $7.7 billion annually, and the livestock and poultry industries overall, which are valued at $87 billion.

The budget proposes an increase in the Veterinary Biologics program by $1.861 million to increase inspections, licensing, and testing of biotechnology-derived veterinary biologics and to enhance tools available to the national animal health laboratory network that would fulfill international standardization requirements. United States sales of agricultural biotechnology products (transgenic seeds [excluding rice and wheat], animal growth hormones, biopesticides, and other products) are projected to increase from $2.4 billion in 2003 to $2.8 billion by 2006, an increase of $144 million annually.

The budget proposes an increase in the Veterinary Diagnostics program by $4.347 million to enhance the national animal health laboratory network and continue its diagnostic work at the Foreign Animal Diseases Diagnostic Laboratory on Plum Island to provide critical services to the animal industry and help protect the United States herd against potential acts of bioterrorism.

The request increases the Agricultural Quarantine Inspection program by $3 million to enhance operations at the National Germplasm and Biotechnology Laboratory to develop technology to detect and identify high-risk plant pathogens as well

as protocols for quarantine testing. These efforts support APHIS' emergency response capabilities, eradication programs, pest exclusion activities, biotechnology permitting programs, and the newly mandated Select Agents program. This increase is offset by a decrease of $2.771 million associated with inter-line inspections in Hawaii and a decrease of $1.246 million for fiscal year 2004 equipment investments.

The budget increases the Import/Export program by $1.355 million to fully develop and begin implementing an automated system to track animal and animal product movements. We are developing this tool in response to increasing global trade and travel and demands for increased efficiency in tracking animals and animal products entering and leaving the country.

FUNDING TO CONTINUE EMERGENCY PROGRAMS

APHIS has been battling several pests and diseases that have entered or unexpectedly spread to new areas of the United States over the past few years. Finishing the job is important if we are to achieve the goals we established when these programs began. Chief among these goals is maintaining export markets. Only by aggressively attacking pest and disease introductions can we assure trading partners that the problems are not endemic to the United States and thus not a reason to ban our products from their markets. The budget requests, and the value of the industries and markets at stake, follow.

—Emerald ash borer, $12.5 million, an increase of $11.009 million. This pest has emerged as a serious pest in the Northern Midwest States and threatens the ash saw timber industry, with a value of $25 billion. Much like the Asian Longhorned Beetle, this pest probably arrived via non-agricultural imports and reflects a new threat; not only do the contents of a container pose a risk, so does the container itself. The budget request would provide for Federal cost-sharing of 75 percent for this program.

—Glassy-winged sharpshooter (vector of Pierce's Disease), $24 million, an increase of $1.881 million. Without a program to control Pierce's Disease, the U.S. wine industry could face losses of $33 billion. The budget request would provide for Federal cost-sharing of 57 percent for this program.

—Citrus Longhorned Beetle (CLHB), $325,000. The CLHB attacks over 40 varieties of hardwood and fruit trees and has no natural enemies. The CLHB could cause $41 billion in losses to forest resources nationwide. The budget request would provide for Federal cost-sharing of 100 percent for this program.

—Citrus Canker, $52.5 million, an increase of $19.071 million. This program protects the Florida citrus industry worth over $9 billion. The budget request would provide for Federal cost-sharing of 57 percent for this program.

—Infectious Salmon Anemia, $235,000. This program protects a part of the burgeoning aquaculture industry—salmon exports of over $100 million annually. The budget request would provide for Federal cost-sharing of 47 percent for this program.

—Spring Viremia of Carp, $285,000. This program protects the common and silver carp industries, with a value of $2.8 billion. The budget request would provide for Federal cost-sharing of 77 percent for this program.

—Chronic Wasting Disease, $20.1 million, an increase of $1.478 million. In addition to the potential spread to other species, this program directly protects the elk farming and antler industry (with annual gross receipts of $150 million) and white-tailed deer farms (with capital investments estimated at $2.5 billion). The budget request would provide for Federal cost-sharing of 77 percent for this program.

—Bovine Tuberculosis, $20.9 million, an increase of $5.998 million. This program protects the entire livestock industry, which has annual earnings from exports of $5.4 billion. The budget request would provide for Federal cost-sharing of 57 percent for this program.

—Scrapie, $20.9 million, an increase of $5.106 million. This program minimizes losses to sheep and goat producers, who currently incur annual losses of $20–25 million because of scrapie. The budget request would provide for Federal cost-sharing of 67 percent for this program.

OTHER INCREASES

We recognize the need for fiscal restraint, but believe that the following additional investments are important if we are to meet the challenges facing us.

—To support the Biotechnology priority, we request an increase of $441,000 for the Animal and Plant Health Regulatory Enforcement program to help ensure compliance by investigating alleged violations of permit restrictions regarding pharmaceutical and industrial plants.

—To further improve our pest and disease surveillance and detection capability—both to protect and gain export markets and to prevent recurring, costly emergency programs—we request $6.171 million for the Fruit Fly Eradication and Detection Program to increase detection trapping in Florida and California.
—To provide the funding requested by the State Department in providing adequate security for APHIS personnel overseas and to continue security and mission critical facilities, we request $7.133 million in our Physical/Operational Security program.
—To establish and maintain liaison positions at key government agencies and to investigate and evaluate disposal techniques for contaminated biological materials, e.g., animal carcasses, we request $932,000 for our Biosecurity program.
—To continue to modernize our information technology infrastructure to include network capacity planning and management, implementation of eGov initiatives, and cyber security compliance and management, we request $891,000 in our APHIS Information Technology Infrastructure program.
—To increase nematode resistant potato varieties and regulatory treatments, we request $184,000 for the Golden Nematode program and to maintain current efficiencies, we request $451,000 in the Screwworm program.

DECREASES

To allow us to fund these high priority programs, we offer key offsets:

With $15.585 million in reduced funding for the Johne's program, APHIS would rely more on the collaborative working relationship between Federal and State animal health workers. For the Boll Weevil program, we are proposing that the Federal Government assume 15 percent of program costs, which in conjunction with the projections of lower nationwide needs, will result in a request of $17 million, a reduction of $33.4 million. To offset the $5 million increase for the wildlife surveillance system, we assume a $5.556 million increase for State cooperators to fund a larger share of the cost of other wildlife management programs such as predator, bird, and invasive species damage. Funding for the Asian longhorned beetle program is requested to be $9.3 million, or a reduction of $20.670 million. The fiscal year 2005 request is based on an overall program level consistent with the $4 million traditionally provided by cooperating (non-Federal) agencies. This would change the program from an eradication program to a control program. The aim is still to protect $41 billion of U.S. forest resources while facilitating the $122 billion trade market with China, the source of the pest.

We also propose a reduction of $10.857 million associated with animal welfare user fees. This will allow the industry to cover an estimated 66 percent of the cost of enforcing the animal welfare regulations.

CONCLUSION

APHIS' mission of safeguarding U.S. agriculture is becoming ever more critical. Although the processes by which we protect America's healthy and diverse food supply are being increasingly challenged, APHIS is committed to taking the lead in building and maintaining a world-class system of pest exclusion, surveillance, detection, diagnosis, and response. Like the APHIS Strategic Plan, the APHIS Budget consists of interdependent components that only when taken together can truly protect the health and value of American agriculture and natural resources.

On behalf of APHIS, I appreciate all of your past support and look forward to even closer working relationships in the future. We are prepared to answer any questions you may have.

PREPARED STATEMENT OF DONNA REIFSCHNEIDER, ADMINISTRATOR, GRAIN INSPECTION, PACKERS AND STOCKYARDS ADMINISTRATION

INTRODUCTION

Mr. Chairman and Members of the Committee, I am pleased to highlight the accomplishments of the Grain Inspection, Packers and Stockyards Administration (GIPSA), and to discuss the fiscal year 2005 budget proposal.

GIPSA is part of USDA's Marketing and Regulatory Programs, which works to support a competitive global marketplace for U.S. agricultural products. GIPSA's mission is to facilitate the marketing of livestock, poultry, meat, cereals, oilseeds, and related agricultural products, and to promote fair and competitive trading practices for the overall benefit of consumers and American agriculture.

GIPSA serves in both service and regulatory capacities. The Packers and Stockyards Programs promote a fair, open, and competitive marketing environment for

the livestock, meat, and poultry industries. The Federal Grain Inspection Service provides the U.S. grain market with Federal quality standards, a uniform system for applying these standards, and impartial, accurate grain quality measurements that promote an equitable and efficient grain marketing system. Overall, GIPSA helps promote and ensure fair and competitive marketing systems for all involved in the merchandising of livestock, meat, poultry, and grain and related products.

ORGANIZATION

GIPSA comprises 737 employees. Grain inspection services are delivered by the national inspection system, a network of Federal, State, and private inspection personnel that is overseen by GIPSA. The system includes 12 GIPSA field offices, 2 Federal/State offices, and 8 State and 58 private agencies that are authorized by GIPSA to provide official services. This network insures the availability of official inspection and weighing services anywhere in the United States. GIPSA also maintains 3 Packers and Stockyards Programs regional offices that specialize in poultry, hogs, and cattle/lamb.

PACKERS AND STOCKYARDS PROGRAMS

GIPSA's Packers and Stockyards Programs (P&SP) administers the Packers and Stockyards Act (P&S Act) to promote fair and open competition, fair trade practices, and financial protection in the livestock, meat packing, meat marketing, and poultry industries. The objective of the P&S Act is to protect producers, growers, market competitors, and consumers against unfair, unjustly discriminatory, or deceptive practices that might be carried out by those subject to the P&S Act. To meet this objective, GIPSA seeks to deter individuals and firms subject to the P&S Act from engaging in anti-competitive behavior, engaging in unfair, deceptive, or unjustly discriminatory trade practices, and failing to pay livestock producers and poultry growers. GIPSA initiates appropriate corrective action when there is evidence that firms or individuals have engaged in anti-competitive, trade, payment or financial practices that violate the P&S Act.

The livestock, meatpacking, and poultry industries are important to American agriculture and the Nation's economy. With only 166 employees, GIPSA regulates these industries, estimated by the Department of Commerce in fiscal year 2002 to have an annual wholesale value of $118 billion. At the close of fiscal year 2003, 5,287 market agencies and dealers, and 2,067 packer buyers were registered with GIPSA. In addition, there were 1,429 facilities that provided stockyard services, with an estimated 6,000 slaughtering and processing packers, meat distributors, brokers and dealers, and 128 poultry firms running 202 poultry complexes operating subject to the P&S Act.

Our regulatory responsibilities are the heart of our mission to administer the P&S Act. To this end, GIPSA closely monitors practices that may violate the P&S Act. Our top priority continues to be investigating complaints alleging anti-competitive, unjustly discriminatory, or unfair practices in the livestock, meat, and poultry industries. Last year, GIPSA conducted over 1,700 investigations. As a result of these investigations, the Packers and Stockyards Programs helped restore over $27 million to the livestock, meatpacking, and poultry industries. While this is not the largest amount GIPSA has ever reported to Congress, it constitutes more than the amount that P&SP received in appropriated funding.

GIPSA divides its regulatory responsibilities into three areas: financial protection, trade practices, and competition. In the area of financial protection, GIPSA continued to provide payment protection to livestock producers and poultry growers in a year where the livestock, meatpacking, and poultry industries faced tremendous financial pressures. Financial investigations last year resulted in $3.2 million being restored to custodial accounts that are established and maintained for the benefit of livestock sellers. Livestock sellers recovered over $1.5 million under the P&S Act's packer trust provisions. During fiscal year 2003, 55 insolvent dealers, market agencies and packers corrected or reduced their insolvencies by $6.6 million. In addition, GIPSA's financial investigators analyzed more than 400 bond claims exceeding $7 million. However, GIPSA has no statutory authority to compel payment by the trustee or bond surety.

In its Trade Practices Programs, GIPSA continued to promote fair trading between industry participants. Much of GIPSA's work in the Trade Practices Program focuses on insuring accurate weights and prices. GIPSA continued to work with local states weights and measures programs to provide scale training and to secure testing of every scale used to weigh livestock or live poultry twice a year. In addition, GIPSA initiated or completed 41 investigations of weight and price manipulation of livestock. Some of these investigations are on-going. GIPSA also investigated

the operations of 143 live poultry dealers; most of these investigations examined whether live poultry dealers were in compliance with contracts entered into with poultry growers. With members of the regulated industries, we developed industry standards on new technologies that are entering the marketplace to evaluate and price livestock purchased on a carcass merit basis. We anticipate implementing two more voluntary standards in the next 6 months.

GIPSA continues to develop its Competition Program. During fiscal year 2003, the Competition Branch began or continues evaluations of 31 complaints regarding attempted restriction of competition, failure to compete, buyers acting in concert to purchase livestock, apportionment of territory, unlawful price discrimination, and predatory pricing. Of these complaints, one firm was brought into compliance, and a second firm went out of business. Six of the investigations revealed that the concerns raised were not supported by evidence. 23 complaints were still pending at the end of the fiscal year. GIPSA continues to work closely with the CFTC, attending CFTC Commissioner briefings on the cattle, hog, and meat markets.

GIPSA's Rapid Response Teams remain a powerful tool to address urgent industry issues that place the industries in imminent financial harm. Last year, GIPSA rapid response teams investigated 59 situations across the Nation. During fiscal year 2003, these rapid response investigations contributed to returning $5.9 million to livestock producers and poultry growers at a cost of $413,010 in salary and travel expenses.

GIPSA continues to work with violating firms to achieve voluntary compliance, and GIPSA continues to initiate appropriate corrective action when we discover evidence that the P&S Act has been willfully violated. During fiscal year 2003, GIPSA, with assistance from the Office of the General Counsel, filed 22 administrative or justice complaints alleging violations of the P&S Act. This number, similar to last year, represents more than a 50 percent increase over the number of complaints filed in fiscal year 2001.

To ensure that producers and growers are aware of the protections the P&S Act provides, the Agency provides a hotline (1–800–998–3447) by which stakeholders and others may anonymously voice their concerns. Last year GIPSA responded to and investigated issues raised by 88 callers. These calls were in addition to calls received in our regional offices. GIPSA also increased its outreach activities. GIPSA conducted 28 orientation sessions for new auction market owners and managers and 4 feed mill orientations to educate them about their fiduciary and other responsibilities under the P&S Act.

It is important to note some of the activities that GIPSA has been engaged with in recent months. Following the discovery of the bovine spongiform encephalopathy (BSE) positive cow in December, 2003, GIPSA created Financial Protection, Trade Practices and Competition Task Forces to provide protection to livestock producers and members of the cattle industry commensurate with its authority under the Packers and Stockyards Act. These task forces are based in Denver, Colorado, GIPSA's cattle office, and include technical experts from each of GIPSA's regional offices and headquarters. The task forces have developed strategies to identify and respond to potentially unlawful practices unique to current market conditions. Daily Agency-wide meetings are being held to inform and share all BSE related information so that employees, task forces, and headquarters are all current on the latest issues.

GIPSA's Financial Protection Task Force is monitoring livestock markets for financial failures. The Task Force has identified scheduled sales at auction markets that were cancelled in the days and weeks following the BSE announcement. It's monitoring firms likely to be more vulnerable to impacts of the BSE incident, identifying industry changes in payment practices, and standing ready to deploy rapid response teams to investigate financial concerns in the industry. GIPSA is currently conducting several investigations of particularly financially vulnerable firms.

GIPSA's Trade Practices Task Force is reviewing changes in marketing and procurement practices implemented by packers in response to the BSE incident. GIPSA has been in contact with major packers and industry groups to stay current on packer responses. GIPSA is reviewing notices sent by packers to livestock producers informing producers of purchasing and pricing changes implemented as a result of BSE. GIPSA has received complaints from producers who claim that packers have changed the payment terms of their contracts and has deployed rapid response teams to investigate these complaints. GIPSA's Competition Task Force is analyzing, and when warranted, investigating cattle markets when anti-competitive practices may be occurring. Several investigations have been initiated. The Competition Task Force analyzes reported fed-cattle prices in various geographic markets to identify abnormal patterns that may indicate violations of the P&S Act. The task force assesses whether price differences are the result of normal market forces, or

packer behavior that may violate Section 202 of the P&S Act. When normal market forces fail to explain abnormal prices, the Competition Task Force conducts a rapid response investigation to determine whether the P&S Act has been violated.

GIPSA has also communicated with the Commodity Futures Trading Commission (CFTC), the Agricultural Marketing Service, Food Safety and Inspection Service, the Animal and Plant Health Inspection Service, and local and State governmental organizations to discuss issues and coordinate plans. GIPSA attends CFTC's surveillance meetings and is prepared to work with CFTC on any investigation that may involve a potential violation of the P&S Act. GIPSA is actively responding to the BSE incident and is prepared to continue enforcement of the Packers and Stockyards Act and regulations in light of this situation.

In addition, this year GIPSA made significant progress on the Livestock and Meat Marketing Study for which Congress appropriated $4.5 million in fiscal year 2003. The study will look at issues surrounding a ban on packer ownership. GIPSA, through APHIS, is in the process of contracting out the study. Since packers' use of non-spot arrangements is intertwined with other advance marketing arrangements throughout the supply chain, the study has a broad focus.

The issues addressed by the study are complex. The research is expected to involve several academic disciplines, varied research methods, and large amounts of data that are not already available. Business schools, economics departments, and agricultural economics departments at universities have indicated an interest in bidding, as have consulting firms. GIPSA expects to see collaborations of disciplines in the bids.

Contractors are expected to complete the study in phases over 2 years, with the first reports due 1 year after contract award. Some descriptive findings will be released prior to completion of the analytical parts of the study. Information about the study, including the Federal Register notice, the public comments, and RFP notices, is available on GIPSA's website at: www.usda.gov/gipsa, by following the "marketing study" icon.

Also in fiscal year 2003, GIPSA completed development of the Swine Contract Library as an internet application that meets the requirements of the Livestock Mandatory Reporting Act of 1999's amendments to the Packers and Stockyards Act. Packers are required to file swine purchase contracts with GIPSA, and monthly reports about the number of swine expected to be delivered, under contract, to packers.

The Swine Contract Library includes information from swine packing plants with a slaughter capacity of 100,000 swine or more per year. 31 firms operating 51 plants accounting for approximately 96 percent of industry slaughter are subject to the SCL. GIPSA has received over 530 contracts to date. In the first 2 months of operation, the SCL recorded more than 1,400 hits. Through the SCL, producers have the ability to see contract terms, including, but not limited to, base price determination formula and the schedules of premiums or discounts, and packers' expected annual contract purchases by region.

The Swine Contract Library went live with information on contract provisions available to the public in early fiscal year 2004, and is available on the GIPSA web site at http://www.usda.gov/gipsa/.

FEDERAL GRAIN INSPECTION SERVICE

GIPSA's Federal Grain Inspection Service (FGIS) facilitates the marketing of U.S. grain in domestic and international markets by providing the market with services and information that effectively and accurately communicate the quality and quantity of grain being traded. GIPSA administers its inspection and weighing programs under the authority of the U.S. Grain Standards Act, as amended, and the Agricultural Marketing Act of 1946 (AMA) as it relates to the inspection of rice, pulses, lentils, and processed grain products.

Providing reliable, high quality inspection and weighing services at a reasonable price remains a key commitment of GIPSA and the State and private officials comprising the official inspection system. Federal export inspection services average $0.30 per metric ton, or approximately 0.23 percent of the $14 billion value of U.S. grain exports. In fiscal year 2003, more than 1.8 million inspections were performed on more than 222 million metric tons of grains and oilseeds. Over 84,000 weighing certificates were issued on 91.5 million metric tons of grain.

There have been many changes in official inspection services over the past several years to respond to changing market demands. GIPSA has programs and services in place to facilitate the loading of shuttle trains; to address greater product differentiation; and to provide customers with inspection results electronically. These

all represent steps in the right direction, but we recognize that the market is changing daily and we must change with it to remain relevant.

GIPSA is focusing on a number of key areas to better facilitate the marketing of U.S. grain. We are enhancing our international outreach capabilities to remove obstacles to U.S. grain reaching world markets. We are bringing standardization to domestic and international markets. We are focusing on providing the market with the information it needs on the end-use functional quality attributes of grain that determine its true value in an increasingly quality-specific market. We are improving service delivery, and the efficiency and cost-effectiveness of the official system.

International outreach is one component of our efforts to facilitate the marketing of U.S. grain. We will continue to expand our outreach efforts to support market development around the world. Our international customers are making great use of the wide array of recently produced multimedia educational materials.

In recent years, we have significantly expanded our outreach efforts to ensure open markets for U.S. grain in Asia and Mexico. Last year, GIPSA initiated two 3-month regional assignments, one in Asia and one in Mexico, to address immediate and long-term grain marketing issues in each region. In Mexico, GIPSA has worked extensively with APPAMEX (an organization of Mexican grain importers), the USDA/Foreign Agricultural Service (FAS), and USDA cooperator organizations to address Mexico's concerns about U.S. grain quality. We have conducted in-depth grain grading seminars to educate Mexican buyers, traders, and end users on the U.S. grain marketing system, GIPSA's impartial grain quality assessment, and U.S. grain standards, sampling procedures, and inspection methods. In fiscal year 2003, GIPSA also helped several of Mexico's private sector grain elevators and processing facilities set up grain inspection laboratories mirrored after GIPSA's. Last fiscal year, we also worked with Mexican and Canadian officials to secure a trilateral agreement on implementation of the Biosafety Protocol.

Our international outreach program also includes technical consultative services for international customers. In fiscal year 2003, GIPSA responded to 17 requests for technical assistance from exporters, importers, and end users of U.S. grains and oilseeds, as well as other USDA agencies, USDA Cooperator organizations, and other governments.

Our international outreach are not the only initiatives we have underway to improve the standardization of, and in turn, facilitate marketing in, domestic and international markets. In the biotech arena, GIPSA is helping bring standardization, consistency, reliability, and accuracy to the biotech testing entities and tools used by the market. GIPSA's test kit evaluation program validates the performance of rapid tests for biotechnology-derived grains and oilseeds. Our Proficiency Program improves the performance and reliability of government and private laboratories in the United States and worldwide that test for biotechnology-derived grains. Under this voluntary program, participants are evaluated based on results of their quantitative and/or qualitative testing of samples of all commercially available corn and soybean biotechnology events. More than 88 organizations participated in the program in fiscal year 2003, a threefold increase from 22 organizations in February 2002.

In fiscal year 2002, GIPSA established formal research collaboration with the National Institute of Science and Technology (NIST) to investigate DNA-based testing for biotechnology-derived grains and oilseeds, and to investigate the development of reference materials and methods for DNA-based testing. Using information obtained through confidentiality agreements with life science organizations, GIPSA and NIST produced event-specific plasmids for evaluation as reference materials and potentially to be in the development of reference methods. In fiscal year 2003, GIPSA and NIST hosted a workshop entitled AStandard Reference Materials for Biotechnology Crops." Thirty-six representatives from the life science organizations, testing laboratories, test kit manufacturers, food processors, Canada, European Union, and Japan attended.

In fiscal year 2004, GIPSA will continue to collaborate with NIST to investigate challenges associated with Polyermase Chain Reaction (PCR) technology and develop reference materials to improve the reliability and accuracy of DNA-based testing and to harmonize testing on a global basis, and will continue to work with NIST to establish global agreement on the development of reference materials for biotechnology-derived grains and oilseeds.

Our market facilitation efforts also include bringing standardized information to markets. In 1999, wheat importers and exporters asked GIPSA to declare that the United States does not produce transgenic wheat. In September 1999, GIPSA began, in accordance with the authority provided under the U.S. Grain Standards Act (7 U.S.C. 79), issuing the following letterhead statement upon an applicant's request: "There are no transgenic wheat varieties for sale or in commercial production in the

United States." The potential deregulation of Round-Up Ready wheat added potential uncertainty to world markets. Wheat industry representatives anticipate that continued issuance of the current statement will be essential to ensure the continued marketing of U.S. wheat. To facilitate the marketing of U.S. wheat if deregulation occurs, GIPSA has agreed to continue issuing the non-transgenic wheat statement, upon request, provided that Monsanto meets several requirements verifying that seed has not been sold for commercial production.

GIPSA also continues to ensure that the official United States standards are responsive to the needs of the domestic marketplace. Developments in plant breeding, the use of new marketing strategies such as identity preservation, increasingly complex processing, food manufacturing, and feed formulation, and other factors will continuously challenge GIPSA to promote current, market-relevant grades and standards that reflect required quality characteristics for specific end uses. In fiscal year 2003, GIPSA proposed creating two subclasses in the class Hard White wheat, which would differ based on seed coat color. Seed coat color can be an important quality factor depending on the target flour product and the miller's flour extraction goal. Also underway are reviews of the soybean standards with a focus on test weight, and the sorghum standards to clarify the various class definitions and to revise the definition of non-grain sorghum.

Working closely with barley producers and the barley malting industry, GIPSA began developing new official criteria called "Injured-by-Sprout" in malting barley. Sprouting occurred in barley in the U.S. Northern Plains region during 2002, which prevented malting barley production contracts from being honored. Barley producers' insurance claims also were denied because official procedures to assess barley sprout damage differ from those used by the malting industry. GIPSA's response is facilitating the marketing of malting barley by enabling USDA's Risk Management Agency to implement the new procedure for the 2004 barley crop year.

Other standards enhancements undertaken to facilitate marketing in fiscal year 2003 include amendments to the U.S. Standards for Rice to establish and add Ahard milled "rice as a new milling degree level and to eliminate the reference Alightly milled." These changes better align the GIPSA standard with current industry processing and marketing standards.

GIPSA knows that customers also need more information about the specific end-use qualities of the products they are purchasing. We are focusing on providing rapid testing of end-use functionality factors to differentiate the functional qualities that meet specific end-use needs.

GIPSA continues cooperative efforts with groups from Canada, Australia, and several European countries to develop and evaluate global artificial neural network (ANN) near-infrared transmittance (NIRT) calibrations for wheat and barley protein. GIPSA conducted a field study on current partial least squares (PLS) wheat protein calibrations and the global ANN calibration. GIPSA also evaluated the field performance of the ANN barley protein calibration. In fiscal year 2004, GIPSA will finalize individual instrument standardization procedures to support implementation of an ANN calibration for wheat and barley protein.

In April 2003, GIPSA convened a meeting of leading North American wheat researchers to generate new avenues of research that would lead to rapid tests for wheat end-use functional characteristics, applicable at the time of inspection and at other points in the value chain. Participants developed a list of quality factors and possible technical approaches for measuring them, with the overarching goal of having a market applicable test ready for use by May 2006. To help keep researchers focused on the task, GIPSA will establish a virtual discussion room for researchers to further collaboration on and support for this effort, and to help researchers find extramural grant sources.

GIPSA is working with the United Soybean Board on their "Better Bean Initiative," a program directed at improving the nutritional composition of U.S. soybean meal and oil. USDA/ARS currently is receiving funding to develop measurement technology for meal and oil. GIPSA is taking part in the Soybean Quality Trait initiative that is seeking to standardize soybean protein, oil, moisture, and fatty acid measurements. GIPSA is part of an inter-laboratory collaborative study to evaluate the consistency of soybean protein, oil, and moisture reference methods. GIPSA is also helping to assemble a soybean sample library suitable for use in developing and evaluating near-infrared (NIR) calibrations.

GIPSA is also exploring new approaches to compliment and supplement our traditional array of services. In fiscal year 2003, GIPSA continued developing a process verification service for grains in response to market demand.

Our efforts to develop new programs did not preclude us from making significant improvements to existing ones. During fiscal year 2003, GIPSA revised the regulations on reinspections and appeal inspections under the U.S. Grain Standards Act

to better reflect market needs and to remove an inefficient, costly, and unnecessary regulatory requirement. Previously, reinspections and appeal inspections for grade included a review of all official factors that may determine the grade, are reported on the original certificate, or are required to be shown. The revised regulations allow interested parties to specify which official factor(s) should be redetermined during the reinspection or appeal inspection service. To safeguard against inadvertent misgrading, official personnel may determine other factors, when deemed necessary. In fiscal year 2004, GIPSA plans to propose a similar action for rice and pulses and other commodities that are inspected for quality factors under the authority of the Agricultural Marketing Act of 1946.

Improving service delivery is essential, as is improving the efficiency and cost-effectiveness of the official system. This will include many initiatives, ranging from harnessing technology to improve operational efficiency and service delivery to making needed program policy changes.

In addition, GIPSA has dedicated resources to homeland security efforts. GIPSA continues to work closely with the USDA Office of Crisis Planning and Management (OCPM) to refine the Department's and the Agency's Continuity of Operations Plan (COOP) and to support and staff the Department's Crisis Action Team (CAT). In fiscal year 2003, GIPSA's COOP and CAT representatives participated in numerous USDA and Marketing and Regulatory Program-sponsored disaster-related exercises and training sessions. They also completed the GIPSA Supplement to the USDA Headquarters COOP Plan, which provides guidance for the continuation/reestablishment of GIPSA's COOP essential functions, including identifying GIPSA's emergency relocation facilities where these functions will be performed and GIPSA personnel who will be required to perform them. The provisions of the GIPSA Supplement, which mirrors the USDA Headquarters COOP Plan, applies only to GIPSA headquarters offices in Washington, D.C.

GIPSA provided technical assistance related to homeland security issues to a number of industry and governmental groups, including the National Grain and Feed Association Safety Committee, the Security Analysis System for U.S. Agriculture (SAS–USA) Technical Advisory Committee, the Interagency Food Working Group, and the USDA Homeland Security Working Group. The Agency is currently working with the National Food Laboratory Steering Committee to coordinate and integrate resources to support the key components of the Food Emergency Response Network (FERN).

GIPSA also continued to face challenges in maintaining an appropriate operating cushion in its user fee account. During fiscal year 2003, GIPSA transferred $2 million from our appropriated account to preclude fiscal over-obligation in violation of the Anti-Deficiency Act. As of May 31, 2003, the cash balance of GIPSA's user fee account had fallen to $2.9 million, a dangerously low amount considering GIPSA's monthly obligations of about $3.0 million.

Due to flat or decreasing exports, and marketing trends that are reducing revenue generated by our current fee structure, there has been a persistent gap between costs and revenue. GIPSA has absorbed losses in its reserve user fee funds. GIPSA has executed many cost-cutting measures to reduce obligations. The Agency has cut employment levels, closed field and sub-offices, streamlined support staffs, and introduced new technology to improve program efficiency.

In the longer term, GIPSA is pursuing several options to preclude future funding difficulties, including implementing a new fee schedule. Program efficiencies, such as streamlining the official inspection processes using a web-based technology and re-engineering program delivery, and opening discussions with stakeholders on how and by whom official inspection services should be delivered to American agriculture were undertaken. 2005 Budget Request

To fund important initiatives and address the Agency's responsibilities, GIPSA's budget request for fiscal year 2005 is $44.1 million under current law for salaries and expenses and $42.5 million for our Inspection and Weighing Services. There is an increase of $662,000 for employee compensation. GIPSA already submitted legislation last fall which would collect $29.0 million in new user fees in fiscal year 2005, $5.8 million for the grain standardization activities and $23.2 million for the Packers and Stockyards Programs. A substantial portion of the IT increases will be one-time only requests.

For grain inspection, the President's fiscal year 2005 budget proposes a current law request of $20.0 million; a total increase of $1.8 million.

An increase of $1,300,000 would allow GIPSA to merge data from several Agency computer information systems for efficient oversight and management of the official grain inspection system and to provide on-demand, Web based access to this data by our partners, customers, and GIPSA personnel. Management needs a single source to capture information about each inspection provided to track work accom-

plishment, technical analysis, and compliance verification. With the information reported, GIPSA will be able to automate the generation of billings records that will be used by the NFC FFIS to generate the invoice for each customer. GIPSA will also use the data system to automatically document and generate a statement of fees owed by each customer on a monthly basis.

By implementing this application, GIPSA will be able to retire two Unix applications and the computer equipment that it runs on. Retiring these Unix applications will allow GIPSA to move towards achieving its goal of a common computing environment within and between FGIS and P&SP, free up one half of a staff year required today for support, and eliminate dependency for support of this application to a single developer.

Also requested is $500,000 to expand GIPSA's technical outreach in key international markets, which is required because GIPSA has experienced a growing demand for cooperative participation with other agencies with international trade responsibilities—for example, State Department, U.S. Trade Representative (USTR), Foreign Agricultural Service (FAS), and the Animal and Plant Health Inspection Service (APHIS)—toward achieving our overall mutual objective of expanding markets for agricultural products and removing barriers to trade.

Modern biotechnology has presented new challenges to U.S. grain markets as many countries develop domestic regulations regarding biotech grains. GIPSA has served the international grain trade community by developing programs to address these emerging needs, and working with related agencies—State, USTR, FAS, and APHIS, among others—to share information regarding these programs and contribute our expertise. For example, China announced broad biosafety regulations 2 years ago that continue to threaten U.S. soybean exports. Partner agencies have sought GIPSA's active participation in negotiations challenging this technical barrier to trade. Such issues are likely to increase in number and frequency in the future.

As another example, a new international environmental treaty, the Biosafety Protocol, which entered into force in September 2003, requires new documentation on biotech grain shipments, and many countries already are developing regulations that are unnecessarily trade-disruptive. During the years ahead, it will be essential for GIPSA to continue in what has been its integral role in an interagency process for implementation of the Protocol by contributing expertise in grain handling, transportation, and marketing, to prevent unnecessary trade disruption.

The funding increase will enable GIPSA to provide personnel on overseas temporary duty to better address and resolve grain trade issues, precluding market disruption due to technical differences in analytical methods and standards; expand U.S. market share due to increased customer satisfaction; and continue to provide critically important technical support as the U.S. government seeks to ensure practical implementation of new regulatory requirements being developed by a growing number of trading partners.

For the Packers and Stockyards Programs, the President's fiscal year 2005 budget proposes a current law request of $24.2 million; a total increase of $3.81 million.

An increase of $1,460,000 for the development of web applications which is required because the current database and application architecture will not support the volume, security, or recovery requirements of GIPSA and USDA as GIPSA moves to support GPEA and OMB and USDA eGov initiatives. Further, the Enterprise Architecture project completed in 2003 identified fifteen (15) business functions that are not supported by any applications within the Packers & Stockyards Programs area, seven of those being key business functions. In addition, the current applications lack integration on the information that is common between the applications, hence requiring duplication (albeit minimal) information entry by program users.

To enable the timely implementation of customer-centric applications within the Packers and Stockyards Program, additional Information Technology developmental resources are required. Currently the Packers and Stockyards Program does not have the web designers or programmers that would allow it to rapidly and accurately deploy Web-based applications. To supplement the current information technology staff and to bring new technology into the program area, GIPSA is requesting contracting funds.

These funds would be used to contract-out the design, development, implementation, and maintenance of important Web initiatives as identified as part of GIPSA's overall Enterprise Architecture and approved by USDA's OCIO. For example, with the requested funding, entities regulated under the Packers and Stockyards Act would be able to register with GIPSA via the internet, electronically file annual reports, and submit bond claims and complaints via the internet. GIPSA would be able to increase its efficiency by electronically verifying bond and trust accounts

with banks, the integration of three stove piped applications, and the real-time tracking of the status and cost of an investigation. (The submission of annual reports alone would save GIPSA over 1,500 hours annually by personnel that are GS14s and 15s.) This would allow the Resident Agents to complete an additional 200 investigations in the future.

An increase of $150,000 is required to operate and maintain the Swine Contract Library (SCL), which is one of GIPSA's Packers and Stockyards Programs' (P&SP) first e-government initiatives. As such, GIPSA has developed an Internet web site that offers packers the opportunity to submit their contracts and anticipated number of hogs procured under contract to GIPSA via a secured connection and producers the opportunity to view contract information via the Internet.

The funding increase will be used to operate and maintain the SCL system. This position will monitor, review, and analyze the contract information and monthly reports submitted by packers, ensure that packers are in compliance by examining submissions for completeness, consistency, and accuracy, conduct confidentiality analysis on information before release, and make the information available at the P&SP regional office and on the GIPSA web site. The increase will also fund Information Technology services and the annual renewal cost for computer software licenses. This IT position will provide software, hardware, and web site maintenance for the SCL program.

An increase of $1,200,000 to support fair and transparent product differentiation and valuation which is required because packers significantly reduced the numbers of livestock purchased based on live weight in recent years. In a stated effort to better meet consumer demand and provide greater "value," packers and producers began trading livestock through contract and marketing agreement or formula-priced transactions. In conjunction with this change in marketing methods, packers explored and began using new means of automating the evaluation of live cattle and hogs, and carcasses based on new technologies, including among other methods, ultrasound and photographic imaging.

Technologies and their applications for evaluating the quality of both live animals and carcasses are changing at an accelerating pace. Previously, carcass merit purchases were generally based on a carcass weight and often one or two grades assigned by USDA graders. Today, packers increasingly rely on internally assigned measures of carcass quality using modern and complex technologies.

Live poultry dealers, as well, are exploring new technologies to assist in evaluating the quality of birds obtained from poultry growers. Implementation of new technologies in the poultry industry may supplement or replace the current methods used by live poultry dealers to determine bird quality and payment to growers, including contract growers.

The technologies now being implemented by packers have a direct effect in determining the prices paid to producers for livestock. Technologies being developed by live poultry dealers will likely affect prices paid to poultry growers. These changes introduce new risks for producers and growers, because these new technologies are not standardized and their accuracy is inconsistent.

This lack of standardization and inconsistent accuracy makes it difficult for producers and growers to detect errors and deliberate changes in the way the technology is used, leaving producers and growers vulnerable to unfair and unjustly discriminatory practices by members of the meat packing and poultry industries. A change that affects as little as one half of 1 percent of the value of livestock in a multi-billion dollar industry can have a huge impact on producers and growers over time. Therefore, P&SP needs to dramatically increase its monitoring and regulatory presence.

This increase in funding will provide P&SP ongoing funding to obtain industrial engineering expertise in the operation of these new electronic evaluation technologies and the methods in which packers and live poultry dealers use them; to develop enforcement tools, investigation techniques and regulatory policies necessary to continue to effectively regulate the meat packing and poultry industries, and when appropriate, initiate enforcement action; to educate and inform the meat packing and poultry industries about responsibilities under the P&S Act with regard to these new technologies; and to educate and inform livestock producers and poultry growers about how the electronic evaluation technologies are used in the meat packing and poultry industries, and how the technologies are regulated by P&SP.

An increase of $1,000,000 is required because immediately following the announcement that a U.S. cow tested positive for BSE, P&SP created task forces to provide protection to livestock producers and members of the cattle industry. These task forces are developing strategies to identify and respond to anti-competitive practices unique to current market conditions; monitor markets for financial failures

and investigate any livestock sale barn or slaughtering facility that closes to ensure that any unpaid cattle sellers are identified and appropriately compensated and investigate complaints related to livestock marketing and procurement contracts.

P&SP regulates 1,429 posted stockyards, 5,287 market agencies and dealers, 2,067 packer-buyers, and 340 bonded packers (those purchasing over $500,000 worth of livestock per year). An additional group of packers that purchase less than $500,000 are also subject to P&SP jurisdiction. A large number of these entities may be adversely impacted as the BSE situation develops, creating circumstances that require immediate P&SP action.

P&SP is developing strategies to identify anti-competitive practices that could occur as a result of current market conditions. These strategies will be implemented and appropriate responses will be initiated where anti-competitive conduct is suspected.

P&SP is looking closely at suspect livestock transactions to ensure that market participants are not taking advantage of the unique market conditions created by the BSE situation. P&SP will deploy rapid response teams to investigate BSE-related complaints. Costs for rapid response investigations related to BSE could easily exceed amounts typically expended on all other rapid response investigations. In the past three fiscal years, P&SP spent $1,372,210 conducting 150 rapid response investigations, or an average of 50 investigations per year at a cost of $457,403.

An increase of $1,200,000 will allow the Agency to establish computer industry standard hardware, software, and facilities to implement the development of customer oriented electronic interfaces to the Federal Grain Inspection Program and the Packers and Stockyards Program. This will allow for a common Information Technology environment for the receipt and delivery of electronic data necessary to efficiently conduct the Agency's programs.

These capabilities will by necessity need to be closely integrated with the existing Information Technology Architecture in GIPSA and conform to the USDA Enterprise Architecture. The computer equipment will be composed of multiple, high performance servers which must accommodate the transfer of very large amounts of data securely and transparently between themselves and the existing Agency information systems. These computer servers must be developed to have the capability to implement a wide range of Web based interactive applications.

Finally, an increase of $1,000,000 is needed because in order to bring the Information Technology Systems security up to an acceptable level within GIPSA, the Agency's network infrastructure must be brought up to the standards as depicted in the USDA Enterprise Architecture. The Agency will need to add network switches, routers and firewalls to bring the network infrastructure up to an acceptable security standard. To insure thorough security planning, the Agency will need funding for additional contractor support in the development of disaster recovery plans, continuity of operations plans, risk analysis, and the certification and accreditation of existing information systems.

CONCLUSION

Mr. Chairman, Members of the Committee, I would like to conclude my testimony on the fiscal year 2005 budget proposal for the Grain Inspection, Packers and Stockyards Administration with an observation.

Technological advances in new products and in business practices create remarkable opportunities and challenges for producers, marketers, and consumers. GIPSA is uniquely situated to facilitate the marketing of products at a time when assurances of product content or production processes are in demand. Further, GIPSA helps ensure that market power by some is not abused. Responding effectively to the needs of our stakeholders requires dynamic activity.

We continue to adapt our efforts, look toward our capabilities, work to understand and accommodate the changes, and serve American agriculture through our efforts to ensure a productive and competitive global marketplace for U.S. agricultural products.

I would be pleased to address any issues or answer any questions that you may have.

Thank you.

STATEMENT OF ELSA A. MURANO

Dr. MURANO. Thank you, Mr. Chairman, Senator Kohl.

I am glad to have the opportunity to speak to you this afternoon regarding the status of the Food Safety and Inspection Service pro-

grams and on our fiscal year 2005 budget request for food safety within the U.S. Department of Agriculture.

As we begin the new year at USDA, I am proud to highlight several areas in which we have used science to improve public health during the past year.

BSE

First, though, I want to briefly touch on the Bovine Spongiform Encephalopathy or BSE issue. Since December 23rd of last year, BSE has been front and center with us, as it has with everyone who has concerns about public health and food safety. Upon learning of the BSE find, we immediately took action to protect the public's health. New regulations were published on January 12th, a mere 2 weeks after the BSE case was announced, truly a remarkable example of how quickly the Bush Administration responded to this threat.

The removal of specified risk material from the food supply, which was the hallmark of these new regulations, was indeed the single most significant step we could have taken to protect the public's health.

SIGNIFICANT FOOD SAFETY ADVANCEMENT OF 2003

The American public remains confident in the safety of the U.S. meat supply, and with good reason. The confidence is due in part to the significant advancements that we have made during 2003. For example, we have seen a dramatic decline in pathogen levels and regulatory samples for Listeria monocytogenes, E. coli O157:H7, and Salmonella. In addition, we had a striking decline in the number of meat and poultry product recalls last year. In fact, the number of class one recalls has nearly been cut in half from the total during 2002. These are dramatic indicators that our scientifically-based policies and programs are working to ensure that the American public receives the safest food possible.

CHALLENGES FOR 2004

Despite these advancements, there is always room for improvement and FSIS has identified challenges for 2004. Through reflection and refinement we have outlined specific initiatives to ensure that we continue to improve health outcomes for American families. These include improving training through the Food Safety Regulatory Essentials program, using the recently established New Technologies Office to promote and accelerate the use of innovative food safety technologies, improving risk assessment coordination to ensure the best available information and science is used in policy development, continuing to conduct baseline studies to determine the nationwide prevalence and levels of various pathogenic organisms in raw meat and poultry, and coordinating with other Federal agencies to strengthen existing efforts to prevent, detect and respond to food related emergencies resulting from acts of terrorism.

FISCAL YEAR 2005 BUDGET REQUEST

I will now turn to the fiscal year 2005 budget request for FSIS. FSIS is requesting a program level of $951.9 million, a net increase of about $61 million from the levels for fiscal year 2004. Under current law, we are requesting an appropriation of $838.7 million with an additional $113 million in existing user fees.

The budget request will fund increased BSE surveillance programs as well as additional training for inspection personnel and numerous programs that will continue to keep us among the leading public health agencies in the world.

The budget request includes a $15.5 million increase for pay raises in Federal and State programs. The budget request includes a $17.3 million increase for humane slaughter enforcement and the full cost of in-plant inspection. Included in this request is $5 million to continue the humane slaughter enforcement work funded in fiscal year 2003.

The remaining $12.3 million of the $17.3 million is for staff support costs that are critically important to maintaining front-line inspection.

The fiscal year 2005 request includes a $33.6 million increase for new initiatives that support our goals at FSIS. First, we include an increase of $3 million for BSE surveillance. The BSE inspection program will add permanent BSE control measures in 2005.

Second, our budget requests $23.5 million to increase support for our Food and Agriculture Defense Initiative. Food contamination and animal and plant diseases and infestations can have catastrophic effects on human health and the economy. So, our portion of the Food and Agriculture Defense Initiative has five components: the Food Emergency Response Network or FERN; data systems to support the Food Emergency Response Network; enhancing FSIS laboratory capabilities; biosurveillance; and follow-up biosecurity training.

To improve the infrastructure under FERN, the budget request calls for a $10 million expansion. Of that funding, $6.1 million would be spent on contracts with state and local laboratories and $2.6 million would be used to establish five regional hubs and a national operating center to coordinate FERN's efforts and conduct training.

The budget request also includes initiatives to support FERN. The Electronic Laboratory Exchange Network, eLEXNET, is a national web-based system that allows laboratories to rapidly report and exchange standardized data. So the budget request of $4 million will be used to make eLEXNET available to additional FERN and other food testing laboratories nationwide.

The budget request includes $2.5 million to enhance our laboratory capabilities for detecting new bioterror-associated agents and to ensure that our capability and capacity to perform toxin and chemical testing is maintained.

The final new initiative is training, which is a very important issue for us. FSIS has been criticized in the past for having insufficiently trained field employees. So, we are working very, very hard to address these concerns and need additional resources in order to significantly improve our training. We are requesting $7.1 million,

over a 50 percent increase in the FSIS training budget for fiscal year 2005. Included in the requested training budget is $3.1 million for our Food Safety Regulatory Essentials training to supplement training for current on and off-line field employees to improve enforcement of HACCP and food safety sampling.

PREPARED STATEMENTS

Thank you again, Mr. Chairman and Senator Kohl, for your attention. And we certainly look forward to responding to your questions.

[The statements follow:]

PREPARED STATEMENT OF DR. ELSA A. MURANO

Mr. Chairman and Members of the Subcommittee, I am glad to have the opportunity to speak with you regarding the status of the Food Safety and Inspection Service (FSIS) programs and on the fiscal year 2005 budget request for food safety within the U.S. Department of Agriculture (USDA).

In Washington, people talk about their inspiring view of the Capitol or the monuments, and the sights that inspire them to work harder and better. The view in my office is quite awesome—at once humbling and challenging. I am referring to a famous portrait on my wall of Louis Pasteur, examining a spinal cord sample. Pasteur disagreed with the popular attitude of the day, "science for science's sake;" he felt that science as a purely academic exercise did not properly serve the people of the 19th century. Instead, he believed that science should have practical applications that could be used to improve the lives of others. As we begin the new year at USDA, I am proud to highlight several areas in which we have used science to improve public health during the past year. I also will share with you our goals for this year, and will conclude with a discussion of the fiscal year 2005 budget request.

First though, I want to briefly touch on the Bovine Spongiform Encephalopathy (BSE) issue. Since December 23, 2003, BSE has been "front and center" with us, as it has with everyone who has concerns about public health and food safety. Upon learning of the BSE find, we immediately took action to protect the public's health. New regulations were published on January 12th, a mere 2 weeks after the BSE case was announced—truly a remarkable example of how quickly the Bush Administration responded to this threat. The removal of specified risk material (SRM) (brain, spinal cord, etc.) from the food supply, which was the hallmark of these new regulations, was indeed the single most significant step we could have taken to protect the public's health. To ensure that these measures are implemented effectively, part of the fiscal year 2005 budget request that I will discuss later consists of $3 million for the agency to conduct surveillance of SRM and advanced meat recovery (AMR). We are confident that the aggressive BSE measures we have developed will continue to protect the U.S. food supply.

SIGNIFICANT FOOD SAFETY ADVANCEMENTS OF 2003

The American public remains confident in the safety of the U.S. meat supply—and with good reason. The confidence is due, in part, to the significant advancements that we made during 2003. One such advancement has been the dramatic decline in pathogen levels in regulatory samples. Late last year, we released data that showed a 25 percent drop in the percentage of positive Listeria monocytogenes samples from the previous year, and a 70 percent decline compared with years prior to the implementation of the Hazard Analysis and Critical Control Point (HACCP) program. In June 2003, to further reduce the incidence of Listeria monocytogenes, we issued regulations for establishments producing ready-to-eat products.

Our measures to prevent E. coli O157:H7 contamination of ground beef have yielded similar results. In September 2002, based on evidence that E. coli O157:H7 is a hazard reasonably likely to occur at all stages of handling raw beef products, FSIS issued a directive requiring all establishments that produce raw beef products to reassess their HACCP plans. Last year, FSIS' scientifically trained personnel conducted the first-ever comprehensive audits of more than 1,000 beef establishments' HACCP plans. A majority of those plants made major improvements based on their reassessments, and, as a result, we are seeing a substantial drop in the percentage of ground beef samples that are positive for E. coli O157:H7. In 2003, of the ground beef samples collected and analyzed for E. coli O157:H7, only 0.30 percent tested positive, compared to 0.78 percent in 2002—a 62 percent reduction. This is a defi-

nite improvement, and the strongest signal that science can drive down the threat from pathogens.

In 2002, we issued new enforcement procedures for the Salmonella performance standard that are paying off. Instead of waiting for three cycles of tests for Salmonella, the failure of the first set now triggers an FSIS review of an establishment's HAACP plan. Due to this process and other science-based initiatives, the percentage of "A" samples (a sample from a randomly scheduled initial set) positive for Salmonella in raw meat and poultry has dropped by 65 percent over the past 6 years. Out of the number of random "A" samples collected and analyzed by FSIS during 2003, only 3.8 percent of the samples were positive for Salmonella, as compared with 10.6 percent in 1998. Again, this is very good news. The data for these three pathogens validate our scientific approach to improving public health through safer food.

We also had a striking decline in the number of meat and poultry product recalls last year. In fact, the number of Class I recalls has nearly been cut in half from the total during 2002. This is a dramatic indicator that our scientifically-based policies and programs are working to ensure that the American public receives the safest food possible.

FSIS has also had great success with its food safety education programs. Through new and innovative methods, FSIS is sharing its food safety message with the general public, including culturally diverse and underserved populations and those at highest risk for foodborne illnesses. From March to November 2003, the USDA Food Safety Mobile traveled over 24,000 miles and participated in 87 events in 64 cities across the country, providing information and publications on food safety to approximately 179,000 people face-to-face and making an estimated 64.4 million media impressions. Another success story is a public service announcement (PSA) featuring former Miss America Heather Whitestone McCallum, which has aired 14,448 times since September 2003. This PSA ranked in the top 3 percent of all PSA's shown during the month of January 2004 along with PSA's by the American Red Cross, the Federal Emergency Management Agency (FEMA), and the Department of Homeland Security (DHS). We are very proud of these far-reaching FSIS food safety education campaigns.

CHALLENGES FOR 2004

Despite the advancements we made last year, there is always room for improvement, and FSIS has identified challenges for 2004. Louis Pasteur said, "In the realm of science, luck is only granted to those who are prepared." Food safety is too important to be left to guess work or luck; we must be prepared to identify and meet challenges head-on.

When I joined USDA over 2 years ago, I established five goals—a roadmap of improvements for our food safety mission:

—To improve the management and effectiveness of our regulatory programs;
—To ensure that policy decisions are based on science;
—To improve coordination of food safety activities with other public health agencies;
—To enhance public education; and
—To protect FSIS regulated products from intentional contamination.

Through reflection and refinement, we have outlined specific initiatives to make sure we fulfill those goals, thereby improving health outcomes for American families. These initiatives were outlined in our food safety vision document, Enhancing Public Health: Strategies for the Future. This detailed plan will continue to drive our policies and actions during this calendar year.

Initiative One: Training

In April 2003, FSIS inaugurated new Food Safety Regulatory Essentials (FSRE) training, which is designed to better equip inspection personnel in verifying an establishment's HACCP food safety system. All trainees received training in the fundamentals of inspection, covering the Rules of Practice, Sanitation Performance Standards, and Sanitation Standard Operating Procedures. FSIS also provides food safety training based on the types of products being produced at the establishments where inspectors are assigned. As of the end of last year, more than 1,000 individuals had completed this training regime.

During 2004, FSIS will continue to train all new entry level slaughter establishment inspectors and veterinary medical officers in technical, regulatory and public health methods. We are also looking at expanding the types of training in the future to meet evolving agency needs and challenges.

Initiative Two: Furthering the Use of Innovative Food Safety Technologies

I believe that we must encourage the use of safe and effective interventions. One way we can encourage such intervention is by hosting public meetings. In January, in Omaha, Nebraska, FSIS held a public meeting to discuss the development and use of new food safety technologies to enhance public health. The meeting generated useful ideas regarding how plants can best utilize new technologies in their operations.

FSIS established a New Technology Office in August 2003. This group is tasked with reviewing new technologies and, where appropriate, expediting the use of new technologies at meat and poultry official establishments and egg products plants. Our New Technology staff is an experienced team of 9 veteran FSIS employees who serve as the single portal for all new technology submissions. We designed this group to better manage the new technology process and allow for implementation as quickly as possible. They also ensure that FSIS personnel are aware of new technologies and where they are being used.

To increase the pool of new technology submissions to the agency, we have established an e-mail address, FSISTechnology@fsis.usda.gov, through which parties may submit their information. I am happy to report that we have received over 30 Notifications and Protocols for new food safety technologies since we have streamlined the submission process. Of the 27 Notifications received, 19 have been issued letters indicating that FSIS has no objections, and 4 are still pending. Once the agency issues a no objection letter, the firm that submitted the proposal may use the new technology.

Initiative Three: Risk Assessment Coordination

In order to better focus its resources on food safety risk assessment activities, FSIS established a risk assessment coordination team with USDA-wide membership. As risk assessment becomes increasingly important as a means of providing the science behind policy decisions, the need for such a group within USDA is clear. This group will promote scientifically sound risk assessments and foster research to support risk assessments.

Microbial risk assessment is still in its infancy compared to chemical risk assessments, so the need to share ideas and resources is critical. In November 2003, we started this interactive process by holding a public meeting to discuss how the government uses the three components of the risk analysis framework—risk assessment, risk management, and risk communication—to inform and implement risk management decisions. In particular, we examined several crucial elements for FSIS to consider in its risk assessments, including how:

—FSIS can improve the transparency of the risk analysis process;
—FSIS can balance the need for transparency, stakeholder involvement and peer review with the need for timely scientific guidance; and
—Risk assessments can better inform policy development and decision-making.

Initiative Four: Developing a Research Agenda

In November 2003, FSIS and the Research, Education and Economics mission area, announced a unified research agenda to coordinate USDA food safety research priorities and needs. For FSIS, research is critical to achieving its public health vision. Although FSIS does not conduct research itself, the agency must identify its research needs based on its public health goals so that the research community can meet them. The unified agenda includes research to:

—Investigate the ecology, epidemiology, virulence and genetic characteristics related to pathogenicity for E. coli O157:H7, Salmonella, Listeria monocytogenes, and other foodborne pathogens to identify targeted control measures;
—Develop effective on-farm, feedlot, transportation, handling, and other pre-processing intervention strategies for reducing the incidence and levels of antibiotic resistant microorganisms and key foodborne pathogens in meat, poultry, eggs and fresh produce;
—Develop, validate, and transfer technology of new and improved processing methods to reduce or eliminate key foodborne pathogens in meat, poultry, fresh produce, seafood, and ready-to-eat foods; and
—Develop rapid and sensitive detection methods for abnormal prions to prevent the possible spread of transmissible spongiform encephalopathies.

Initiative Five: To Develop Best Practices for Animal Production

In consultation with producers, researchers, and other stakeholders, FSIS is developing a list of best management practices for animal production in order to provide guidance for reducing pathogen loads before slaughter.

Last September, FSIS arranged a symposium with USDA partners to discuss ways to significantly reduce the levels of E. coli O157:H7 in live animals before slaughter. We understand that preventing the spread of E. coli and other pathogens on the farm is vital to increasing food safety and protecting public health. The dialogue generated at the meeting helped us develop guidelines outlining the best management practices at the pre-harvest stage, which we expect to publish this year. Once these guidelines are published, FSIS will initiate an aggressive outreach effort to distribute them to producers.

Initiative Six: Baseline Studies

It is imperative that FSIS develops baseline studies. FSIS is developing protocols to conduct continuous baseline studies to determine the nationwide prevalence and levels of various pathogenic microorganisms in raw meat and poultry. The studies will help the agency and the industry to better understand what interventions are working or how they could be improved. To achieve the agency's goal of applying science to all policy decisions, the fiscal year 2004 budget included a new $1.7 million initiative to establish a continuous baseline program for risk assessments and performance measurement.

In the past, baseline studies have been used to establish pathogen reduction performance standards, which are an important part of verifying the sanitary operation of meat and poultry establishments. The new baseline studies will take into account regional variation, seasonality and other critical factors.

The continuing nature of the baseline studies will provide information on national trends and a tool to assess performance of initiatives designed to reduce the prevalence of pathogens in meat and poultry products. These baseline studies will also yield important information for conducting risk assessments that can outline steps we can take to reduce foodborne illness.

These surveys will also be important in establishing the link between foodborne disease and ecological niches, as well as levels and incidence of pathogens in meat and poultry. The net result will be more targeted interventions and the effective elimination of sources of foodborne microorganisms.

Initiative Seven: Food Biosecurity

While the events of September 11, 2001, brought the issue of the vulnerability of our food supply to the forefront, FSIS' food biosecurity efforts did not start on September 12, 2001. FSIS' 100 plus years worth of experience in dealing with food emergencies have allowed the agency to develop the expertise to protect the U.S. meat, poultry, and egg products supply wherever and whenever emergencies or new threats arise.

It is imperative that FSIS coordinates with other public health agencies to protect the food supply against intentional harm. The agency has improved such coordination, as well as strengthened existing efforts to prevent, detect, and respond to food-related emergencies resulting from acts of terrorism. With a strong food safety infrastructure already in place, FSIS has been able to focus on strengthening existing programs and improving lines of communication, both internally and externally. Later, when I discuss the fiscal year 2005 budget request, I will describe the components of our food and agriculture defense initiative.

ACHIEVING THE NEXT LEVEL OF FOOD SAFETY

The emergence of previously unrecognized pathogens, as well as new trends in food distribution and consumption, highlights our need for new strategies to reduce the health risks associated with pathogenic microorganisms in meat, poultry and egg products. Through analysis and discussions with stakeholders, we have identified three issues that need to be addressed to attain the next level of public health protection.

Issue One: To anticipate/predict risk through enhanced data integration

To better anticipate risks involving meat and poultry products, we must have the best available data to clearly identify the extent and nature of these risks, so that we may determine an effective response. These data consist of regulatory samples, as well as samples collected by food processing establishments. Thus, we must improve data analysis while encouraging data sharing from all reliable sources.

With regard to food biosecurity, FSIS works closely with the White House Homeland Security Council, DHS, the Food and Drug Administration (FDA) and the USDA Homeland Security Staff to develop strategies to protect the food supply from an intentional attack. For example, FSIS, along with FDA and industry partners, is working with DHS to establish new food information sharing and analysis activity for the food sector. This public/private partnership will aid in the protection of the

critical food infrastructure by centralizing the information about threats, incidents, and vulnerabilities.

Issue Two: To improve the application of risk analysis to regulatory and enforcement activities

Food safety problems need to be documented as they occur, so that conditions may be analyzed and, if need be, corrected. A better understanding of the prevalence and causes of food safety failures could allow better assessment of how to best address them. Data regarding the causes of food safety violations, either within a specific establishment, or within a class of establishments, can be utilized in order to better focus prevention and regulatory enforcement strategies.

FSIS is exploring the development of a real-time measure of how well an establishment controls the biological, chemical, and physical hazards inherent in its operations. Such a predictive model would help the agency make resource allocation decisions across the country's more than 6,000 meat and poultry establishments to maximize food safety and public health protection.

Issue Three: To better associate program outcomes with public health surveillance data

We have seen notable advances in preventing foodborne illness, which the Centers for Disease Control and Prevention (CDC) have attributed, in part, to the implementation of HACCP. However, there still is a need to determine how specific policies affect public health. In order to accomplish this, we need to obtain and document data that links foodborne illness outbreaks with specific foods. It may then be linked with prevalence data of specific pathogens in specific foods. However, to complete the linkage with public health outcomes, we need accurate and timely human health surveillance data.

We have already taken steps to secure such surveillance data, and we continue to update our systems. In 1995, FSIS worked with CDC, FDA, and public health laboratories in several States to establish FoodNet, the Foodborne Diseases Active Surveillance Network, as part of CDC's Emerging Infections Program.

FoodNet includes active surveillance of foodborne diseases, case-control studies to identify risk factors for acquiring foodborne illness, and surveys to assess medical and laboratory practices related to foodborne illness diagnosis. FoodNet provides estimates of foodborne illness and sources of specific diseases that are usually found in the United States, and interprets these trends over time. Data are used to help analyze the effectiveness of the Pathogen Reduction/Hazard Analysis and Critical Control Point rule and other regulatory actions, as well as public education aimed at decreasing foodborne disease in the United States. We are also considering establishing a joint task force with CDC to determine ways to improve FoodNet.

In addition to data collected through FoodNet, FSIS is a partner with CDC and State agencies in PulseNet, a national computer network of public health laboratories that helps to rapidly identify outbreaks of foodborne illness. Laboratories perform DNA "fingerprinting" on bacteria that may be foodborne, then the network permits rapid comparison of the "fingerprint" patterns through a CDC database. PulseNet is an early warning system that links seemingly sporadic illnesses, and enables public health officials to more quickly identify and react to the emergence of multi-State illness outbreaks.

FSIS is also working with CDC's National Center for Infectious Diseases to design and support studies that enable definite connections to be made between occurrence of specific pathogens in specific foods and the occurrence of human foodborne illness.

FoodNet, PulseNet and other similar programs are excellent examples of Federal and State agencies working together to accomplish public health goals. These programs will help FSIS and other regulatory agencies to focus inspection and enforcement on those practices where risk is deemed to be highest, resulting in a more efficient use of government resources.

FISCAL YEAR 2005 BUDGET REQUEST

I will now turn to the fiscal year 2005 budget request for FSIS. In fiscal year 2005, FSIS is requesting a program level of $951.7 million, a net increase of about $61 million from the enacted level for fiscal year 2004. Under current law, we are requesting an appropriation of $838.7 million, with an additional $113 million in existing user fees. The budget request will fund the increased BSE surveillance programs I mentioned earlier, as well as additional training for inspection personnel and numerous programs that will continue to keep FSIS among the leading public health agencies in the world. By continuing the principle of making policy based on sound science, we will modernize our inspection system to handle the challenges of

food safety in this century. Implementation of these budget initiatives is imperative to help us attain the public health vision we have set for FSIS.

Supporting FSIS' Basic Mission

The FSIS budget request for fiscal year 2005 supports the agency's basic mission of providing continuous food safety inspection in each meat, poultry, and egg products establishment in the United States. The budget request includes a $15.5 million increase for pay raises in Federal and State programs. In addition, the budget supports an agency-wide staff-year ceiling of 9,641, an 84 staff year increase from the 2004 appropriation level. The budget reflects the proposed calendar year 2005 pay raise of 1.5 percent for Federal and State personnel, a 0.2 percent increase for employee rewards, and the annualized cost of the 4.1 percent pay increase for calendar year 2004. The costs also include a total net increase of approximately $721,000 for state food safety and inspection.

Two critical elements of FSIS' mission are to continue the enforcement of humane slaughter regulations and to provide for the full cost of front-line inspection. FSIS will continue strict enforcement of its regulations for the humane handling and slaughter of livestock. In fiscal year 2003, over 7,600 inspection personnel stationed in over 6,000 federally inspected meat, poultry, and egg products plants verified that the processing of 43.6 billion pounds of red meat, 49.2 billion pounds of poultry, and 3.7 billion pounds of liquid egg products complied with statutory requirements. The fiscal year 2005 budget request includes a $17.3 million increase for humane slaughter enforcement and the full cost of in-plant inspection. Included in the request is $5.0 million to continue the work funded in fiscal year 2003 for fiscal year 2003 through fiscal year 2004.

The remaining $12.3 million of the $17.3 million is for staff support costs that are critically important to maintaining front line inspection. Over 80 percent of FSIS costs are for salaries, benefits, and travel costs for inspectors to travel between plants. Increases in benefit and travel costs cannot be deferred to another year. The agency's share of employee benefits costs has been rising in recent years by over $4 million annually. The agency has also experienced large increases in retirement costs, hiring incentives, and employee allowances for the purchase of safety equipment and related items. The increase is needed to avoid employment restrictions in the inspection program, which would result if unavoidable cost increases are not fully funded and must be absorbed.

New Initiatives

The fiscal year 2005 request includes a $33.6 million increase for new initiatives that support the Department's goals for FSIS.

First, as I discussed in my opening, the fiscal year 2005 budget request includes an increase of $3 million for BSE surveillance. FSIS' BSE inspection program will add permanent BSE control measures in fiscal year 2005. These control measures will include increased in-plant verification of slaughter plant designs for controlling SRMs, overtime inspection, and travel for Veterinary Medical Officers to test non-ambulatory disabled livestock when they arrive at small slaughter plants that do not have a resident veterinarian. In fiscal year 2005, FSIS will also perform about 60,000 screening tests at processing plants that use AMR equipment, to ensure that SRMs do not enter the food supply.

The fiscal year 2005 budget also requests a $23.5 million increase to support our food and agriculture defense initiative. Food contamination and animal and plant diseases and infestations can have catastrophic effects on human health and the economy. USDA, the Department of Health and Human Services and DHS are working together to create a comprehensive food and agriculture policy that will improve the government's ability to respond to the dangers of disease, pests and poisons, whether natural or intentionally introduced. FSIS' portion of the food and agriculture defense initiative has five components:

—Biosurveillance;
—The Food Emergency Response Network;
—Data systems to support the Food Emergency Response Network;
—Enhancing FSIS laboratory capabilities; and
—Follow-up biosecurity training.

To finance the biosurveillance component of the food and agriculture defense initiative, the fiscal year 2005 budget requests $5 million. The Homeland Security Council (HSC) Biodefense End-to-End Assessment, in cooperation with all relevant U.S. Government agencies, identified early attack warning and surveillance as a top priority to prepare against a potential bioterrorist attack. The HSC supports an interagency biosurveillance initiative to improve the Federal Government's ability to rapidly identify and characterize such an attack. This initiative will improve Fed-

eral surveillance capabilities in human health, food, agriculture, and environmental monitoring. It will also allow Federal agencies to establish integration capability at DHS so that DHS may rapidly compile these streams of data and integrate them with threat information.

FSIS has conducted its own vulnerability assessments of regulated domestic and imported products. The assessments identify potentially vulnerable products and processes, likely threat agents, and points along the production/consumption continuum where attack is most likely to occur. The agency will focus its resources on the points of greatest vulnerability.

The second component of the food and agriculture defense initiative is the Food Emergency Response Network (FERN). A nationwide laboratory system with sufficient capacity to meet the needs of anticipated emergences is integral to any bioterror surveillance and monitoring system. FERN consists of Federal and State governmental laboratories which are responsible for protecting citizens and the food supply from intentional acts of biological, chemical, and radiological terrorism. Currently, over 60 laboratories, including public health and veterinary diagnostic laboratories, representing 27 States and five Federal agencies, have agreed to participate in FERN. The goal is to establish 100 FERN laboratories, creating a network of Federal, State and local laboratories that FSIS could call upon to handle the numerous samples that would be required to be tested in the event of a terrorist attack on the meat, poultry or egg supply.

To improve the infrastructure under FERN, the budget request calls for a $10 million expansion. Of that funding, $6.1 million would be spent on contracts with State and local laboratories, and $2.6 million would be used to establish five Regional Hubs and a National Operating Center to coordinate FERN's efforts and conduct training. In addition, during fiscal year 2005, FSIS would also use $1.3 million to establish five to seven State laboratories for screening of microbiological agents, with more laboratories in the future, based on the availability of funds. The staff of these laboratories will receive training, perform methods validation, and analyze surveillance and check samples.

The third and fourth components of the food and agriculture defense initiative support FERN. The electronic laboratory exchange network (eLEXNET) is a national, web-based system that allows laboratories to rapidly report and exchange standardized data. The fiscal year 2005 budget request of $4 million will be used to make eLEXNET available to additional FERN and other food-testing laboratories nationwide. Access to properly validated methods used for screening, confirmation, and forensic analysis is critical to all laboratories, and laboratories need rapid access to new or improved methods that use emerging technologies, have greater sensitivity, or are more efficient. FSIS is working with FDA to develop a web-based repository of analytical methods that is compatible with eLEXNET. The budget request also includes $2.5 million to enhance FSIS' laboratory capabilities for detecting new bioterror-associated agents, and to ensure FSIS' capability and capacity to perform the toxin and chemical testing that will be standardized across all FERN laboratories.

The final component of the food and agriculture defense initiative is follow-up biosecurity training for the workforce. Follow-up training is essential as part of the ongoing effort to protect the public by educating the workforce regarding the latest threat agents and countermeasures to those agents. The budget request includes $2 million for follow-up training for fiscal year 2005.

The final new initiative I will discuss is training. FSIS has been criticized over the years by the General Accounting Office and the Office of the Inspector General for having poorly trained field employees. We have been addressing these concerns over the last year, but need additional resources in order to significantly improve our training. We are requesting $7.1 million—over a 50 percent increase—in the FSIS training budget for fiscal year 2005. Of the requested training budget, $4.0 million would be used to increase the number of entry level inspectors receiving formal classroom training from 20 percent to 100 percent. Under this proposal, all new inspectors will receive formal training on how to identify and respond to food safety problems. New employees will be required to demonstrate mastery of training in order to be certified to assume inspection duties.

The requested training budget also includes $3.1 million for Food Safety Regulatory Essentials training, to supplement training for current on- and off-line field employees to improve enforcement of Pathogen Reduction/Hazard Analysis and Critical Control Point regulations and food safety sampling. These frontline employees are responsible for making the critical decisions to ensure that products are safe to eat, so it is essential to have a scientifically and technically trained workforce.

User Fee Proposal

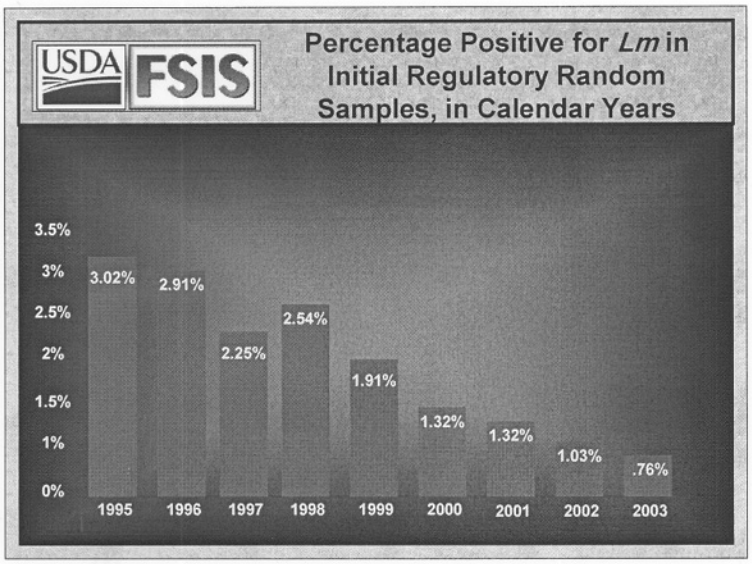
FSIS' fiscal year 2005 budget also includes a legislative proposal to recover the costs of providing inspection services beyond an approved 8-hour primary shift. The proposal was submitted to Congress last August. If the proposal is enacted, the level of appropriated funds needed would be reduced by an estimated $124 million, making the FSIS budget request $714.7 million. Under current law in 2005, FSIS estimates it will collect $113 million in annual user fees to recover the costs of overtime, holiday, and voluntary inspection.

CLOSING

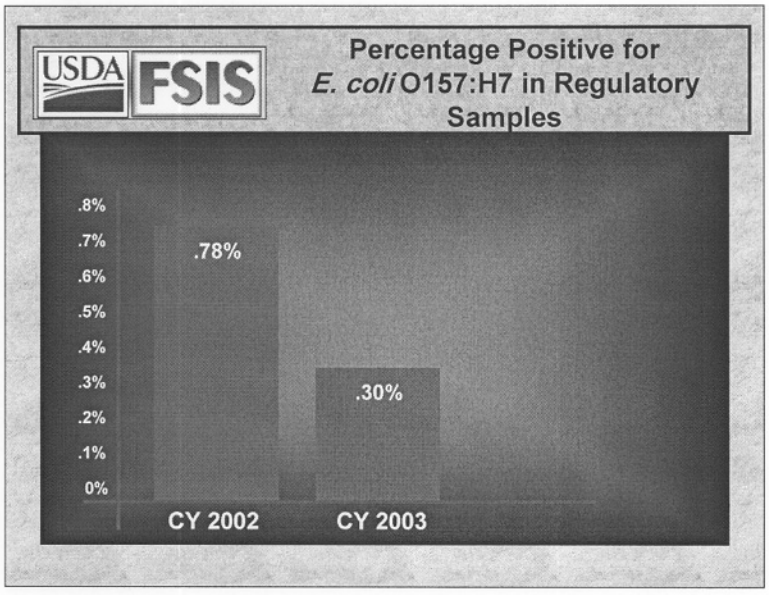
We intend to continue to engage the scientific community, public health experts and all interested parties in an effort to identify science-based solutions to public health issues to ensure positive public health outcomes. It is our intention to pursue such a course of action this year in as transparent and inclusive a manner as is possible. The strategies I discussed today will help FSIS continue to pursue its goals and achieve its mission of reducing foodborne illness.

Mr. Chairman, thank you again for providing me with the opportunity to speak with the Subcommittee and submit testimony regarding the steps that FSIS is taking to remain the world leader in public health. I look forward to working with you to improve our food safety system, ensuring that we continue to have the safest food supply in the world.

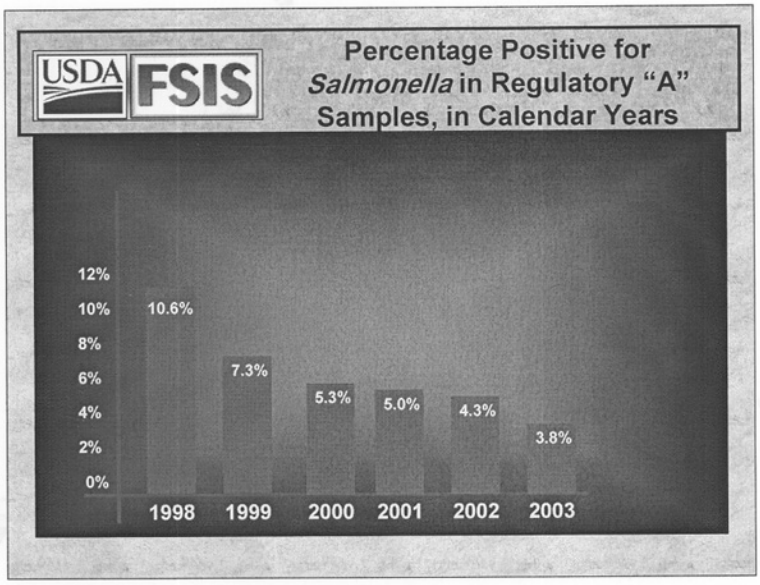
Percentage Positive – *Lm*



Percentage Positive – *E. coli* O157:H7

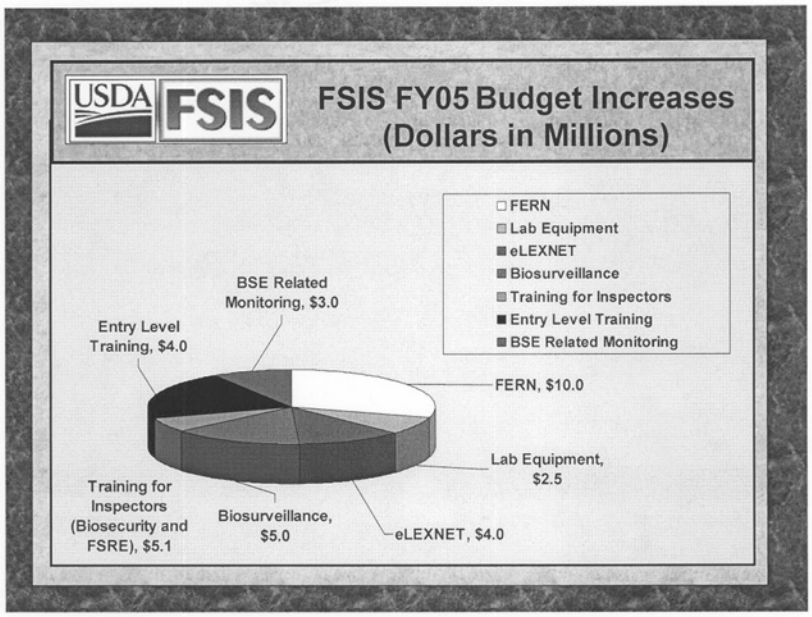


Percentage Positive – *Salmonella*



Total Recalls

FY 2005 Budget Request



PREPARED STATEMENT OF DR. BARBARA J. MASTERS, ACTING ADMINISTRATOR, FOOD SAFETY AND INSPECTION SERVICE

Mr. Chairman and distinguished members of the Subcommittee, I am pleased to be here today as we discuss public health and the U.S. Department of Agriculture's (USDA) fiscal year 2005 budget request for the Food Safety and Inspection Service (FSIS).

Infrastructure

FSIS has a long, proud history of protecting public health. Although the Agency under its current name was established by the Secretary of Agriculture on June 17, 1981, its history dates back to 1906. FSIS' mission is to ensure that meat, poultry, and egg products prepared for use as human food are safe, secure, wholesome, and accurately labeled. FSIS is charged with administering and enforcing the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), the Egg Products Inspection Act (EPIA), and the regulations that implement these laws.

Ensuring the safety of meat, poultry, and egg products requires a strong infrastructure. To accomplish this task, FSIS has a large workforce of approximately 10,000 employees, most of who are stationed in the field, dedicated to inspection. In fiscal year 2003, over 7,600 inspection personnel stationed in over 6,000 federally inspected meat, poultry, and egg products plants verified that the processing of 43.6 billion pounds of red meat, 49.2 billion pounds of poultry, and 3.7 billion pounds of liquid egg products complied with statutory requirements. In addition, we re-inspected 3.8 billion pounds of imported meat, poultry and processed egg products from 28 of 33 countries that we determined have inspection systems equivalent to our own. Assuring that these products are safe and wholesome is a serious responsibility.

As you are well aware, these are compelling times in food safety, and it is because of your support that we are making real progress in improving the safety of the U.S. food supply. I would like to thank you for the past support you have given us in our budget requests. Now, I would like to tell you how we are fulfilling our responsibilities through FSIS' food safety vision and about our initiatives for better ensuring the safety of meat, poultry, and egg products.

Fulfilling the Vision

The continued mission of FSIS is to ensure that consumers have the safest possible food supply. To fulfill this vision, we have set out to continuously modernize FSIS' ability to improve the safety of meat, poultry, and egg products. Our efforts are paying off, as seen by the 16 percent decline in foodborne illness over the last 6 years. The Centers for Disease Control and Prevention (CDC) attributes these results in part to the implementation of the Hazard Analysis Critical Control Point (HACCP) system in all meat and poultry plants in the United States. However, in spite of these positive trends towards a safer food supply, FSIS recognizes that intensified efforts are needed to reach the next level of food safety. That is why the agency has diligently worked to carry out Dr. Murano's five core goals:

—To improve the management and effectiveness of our regulatory programs;
—To ensure that policy decisions are based on science;
—To improve coordination of food safety activities with other public health agencies;
—To enhance public education; and
—To protect FSIS regulated products from intentional contamination.

Improving the Management and Effectiveness of Regulatory Programs

In order for policies and programs to be successful, they must be uniformly and correctly applied. Thus, proper training of the workforce is essential. In addition, communication to field personnel needs to be timely and accurate, with proper supervision from the district and from headquarters in order to foster accountability in the system.

Training and Education

The key to improving the management and effectiveness of FSIS' considerable infrastructure is to ensure that the agency is well prepared with the tools necessary to protect the food supply. Training is a top priority of the agency. FSIS can only achieve its public health, food safety, and food security mission with adequate preparation of its workforce through scientific and technical training.

In April 2003, FSIS began the Food Safety Regulatory Essentials (FSRE). The goal of the training is to teach inspection personnel how to do their jobs properly, and emphasizes the regulatory decision-making thought process both through lecture and workshop examples. In fiscal year 2003, FSIS exceeded its goal to train 800 inspectors under FSRE. A comparison between pre-test and post-test scores has shown that the knowledge improvement of our inspectors has increased by an average of 20 percent. Feedback from our inspectors has been extremely positive, and industry representatives have noted the positive difference that these courses are having on how inspection procedures are performed.

FSIS has also initiated a comprehensive 2-year training and education effort designed to ensure that every FSIS employee fully understands their role in preventing or responding to an attack on the food supply. Last year, over 1,600 employees received food security training. By the end of fiscal year 2004, over half of our workforce will have received this training. The Law Enforcement Academic Research Network (LEARN), which is carrying out the training, has stated that this training effort is unparalleled in the Federal sector since it is being provided to such a broad base of our employees.

Another initiative the agency has undertaken to enhance FSIS' training effort is taking training opportunities closer to our employees. In August 2003, the agency announced new regional training centers designed to bring comprehensive workforce training programs to FSIS field employees throughout the country. FSIS has established the regional training centers in five field locations: Atlanta, GA; Dallas, TX; Philadelphia, PA; Des Moines, IA; and Boulder, CO. FSIS has hired three of the regional trainers to head the new centers, and expects to hire the remaining two trainers by April. In addition, FSIS will be providing distance learning that will be easily accessible to our field employees. These approaches will allow FSIS to train more inspectors each year in various skills to enhance their technical and regulatory abilities.

Another step we've taken is to increase our cadre of scientifically trained personnel, known as Consumer Safety Officers (CSOs). CSOs have a scientific and technical background and receive additional FSIS training that enables them to use a disciplined methodology to assess and verify the design of food safety systems. FSIS has trained every entering CSO—150 of them—in a cooperative agreement through the Texas Agricultural Experiment Station. In fiscal year 2004, the agency plans to train 200 additional employees in this program, including employees who have been promoted to CSOs, Veterinary Medical Officers, Program Investigators, and others.

Accountability

FSIS inspection personnel are held accountable for ensuring that public health is protected. To emphasize the importance of accountability, FSIS created the Office of Program Evaluation, Enforcement and Review (PEER) during the agency's recent reorganization. PEER serves as a quality control team by ensuring that FSIS functions, such as reviews of plants for compliance and food safety investigations, are carried out in a way most conducive to protecting the public health. PEER retains the role of ensuring prompt and appropriate enforcement of the inspection laws. The work of the field Program Investigators in PEER places them on a daily basis in close proximity to performance and compliance problems and concerns at the in-plant level, which affords the agency the ability to deal with necessary adjustments and problems in a much more immediate and direct fashion than in the past. PEER was formed because a strong quality assurance program that uses reviews, evaluations, and audits as its tools can have a significant impact on management effectiveness, efficiency and policy development.

Because accountability is crucial in delivering programs in a consistent and effective manner, FSIS implemented the Humane Activities Tracking (HAT) program in February 2004. This new electronic tracking system will document inspection activities to ensure that livestock are humanely handled and slaughtered in federally inspected facilities. The HAT program will provide FSIS with more accurate and complete data on the time spent by FSIS personnel performing nine specific humane handling related tasks to ensure humane handling and slaughter requirements are met.

In addition, in November of 2003, FSIS issued an updated directive to all inspection personnel and district offices providing specific, detailed information about requirements of the Humane Methods of Slaughter Act to ensure that verification and enforcement requirements are clearly and uniformly understood. In May of 2003, FSIS also issued a directive to provide guidance and direction to inspection personnel to ensure consistent use of enforcement actions.

ENSURE THAT POLICY DECISIONS ARE BASED ON SCIENCE

FSIS continuously reviews its existing authorities and regulations to ensure that emerging food safety challenges are adequately addressed. In addition, FSIS is committed to continuing its emphasis on the use of science, research, and technology in the development of improved food safety policies, focused on prevention whenever possible.

Risk Assessment

Risk assessment is one tool that can provide FSIS with the solid scientific foundation on which to base regulatory and policy decisions. In fact, the Agency has used risk assessment to estimate the likelihood of exposure to various hazards, and to estimate the resulting public health impact. For example, in February 2003, FSIS released a draft of a quantitative risk assessment conducted on Listeria in ready-to-eat (RTE) meat and poultry products. On February 26, 2003, FSIS held a public meeting to discuss the design of the risk assessment, the results, and conclusions that could be drawn from it regarding the risk of contamination of RTE products with this pathogen during processing.

The Listeria risk assessment, in conjunction with a previously released Food and Drug Administration (FDA)/FSIS risk ranking, peer review, and public comment, provided important data enabling FSIS on June 6 to publish a final Listeria rule originally proposed in early 2001. This risk-based regulation will serve as the cornerstone of the FSIS efforts to prevent listeriosis from RTE meat and poultry products. The rule requires all establishments that produce RTE products that are exposed to the environment after cooking to develop written programs to control Listeria monocytogenes and to verify the effectiveness of those programs through testing. Establishments must share testing data and plant-generated information relevant to their controls with FSIS. The rule also encourages all establishments to employ additional and more effective Listeria monocytogenes control measures.

Innovative Testing Methods

In October 2003, FSIS announced the adoption of the BAX® system to screen for Salmonella in raw meat and poultry products. The Microbial Outbreak and Special Projects Laboratory, in collaboration with three FSIS field service laboratories, evaluated the BAX® system to determine whether it would be beneficial to the agency and to determine its validity and reliability. FSIS determined that the BAX® system was as sensitive as the existing method of detecting Salmonella in raw meat and poultry products, but also reduced the reporting time for negative samples by one to 2 days. FSIS has been using the BAX® screening system for Salmonella in

ready-to-eat meat, poultry and pasteurized egg products since February 2003, and for Listeria monocytogenes since April 2002. This new measure increases efficiency in detecting pathogens and saves valuable agency time and resources.

Reducing E. coli O157:H7

FSIS has instituted major changes in its E. coli O157:H7 policy to further ensure that beef plants address and reduce the presence of E. coli O157:H7. In October 2002, the agency took strong steps to address E. coli O157:H7 contamination based on USDA's Agricultural Research Service's data and FSIS' draft risk assessment. Those measures are starting to pay dividends to the American consumer. Our scientifically trained personnel have examined prevention mechanisms at more than 1,000 beef establishments and a majority of those plants have made major improvements based on reassessments of their HACCP plans. As a result, we are seeing a drop in the number of E. coli O157:H7 positive samples in ground beef. For instance, in E. coli O157:H7 samples collected and analyzed during 2003, 0.30 percent tested positive, compared to 0.78 in 2002—or a 62 percent reduction.

IMPROVE COORDINATION OF FOOD SAFETY ACTIVITIES WITH OTHER PUBLIC HEALTH AGENCIES

With primary authority over meat, poultry, and egg products, FSIS plays an integral role in ensuring the safety of America's food supply. As one partner in the U.S. food safety effort, FSIS strives to maintain a strong working relationship with its sister public health agencies. Cooperation, communication, and coordination are absolutely essential if we are to be effective in addressing public health issues.

BSE Coordination

The December 2003 discovery of a single case of Bovine Spongiform Encephalopathy (BSE) in Washington State provides an excellent example of the strong communication ties and the cooperation between USDA and its Federal and State food safety partners. The Federal Government's swift and substantial reaction to the BSE diagnosis played a vital role in maintaining high consumer confidence. FSIS and its sister agencies moved effectively and forcefully upon the discovery of a BSE case in this country, further strengthening already formidable BSE preventive measures. Being a part of the continuous briefings, planning meetings, international trade discussions, and all the other events surrounding this situation has been both challenging and rewarding. FSIS has worked closely with USDA's Animal and Plant Health Inspection Service (APHIS) and other mission areas in USDA, FDA, state governments, industry and consumers to ensure our BSE prevention and response measures are fully effective in the United States.

MOU with FDA

Since 1999, FSIS and the Food and Drug Administration (FDA) have had a Memorandum of Understanding (MOU) to exchange information on an on-going basis about establishments that fall under both jurisdictions. FSIS will continue engaging in substantive discussions with FDA and other agencies who share public health and food safety responsibilities. The Bioterrorism Act of 2001 (Public Law 107–188) further enhanced this cooperation by authorizing FDA to commission FSIS employees to conduct inspection at dual jurisdiction facilities.

Public Health Service Commissioned Corps Officers

In addition to its partnerships with the White House and Federal agencies, FSIS has entered into a working relationship with the U.S. Public Health Service (PHS) and the Office of the Surgeon General. In April 2003, FSIS signed a Memorandum of Agreement with the Surgeon General and the PHS that allows expanded numbers of PHS Commissioned Corps Officers to be detailed to the agency. FSIS currently has 19 PHS Commissioned Corps Officers detailed to the agency and will incorporate additional PHS Officers nationwide across all program areas under the agreement. Not only will these officers help FSIS respond to foodborne disease outbreaks and assist in preventing foodborne illness, but they will assist in the agency's homeland security efforts as well. Since the Commissioned Corps Officers are available 24 hours a day, 7 days a week, this affords a greater flexibility to respond immediately during heightened security alerts or an actual threat to the food supply.

USDA's Unified Food Safety Research Agenda

Another example of FSIS' commitment to communication, cooperation, and coordination was the November 2003 announcement of a unified food safety research agenda to improve the efficiency and effectiveness of food safety programs. USDA also released a list of additional research needs specific to meat, poultry and egg products that FSIS will encourage non-governmental entities to address. The gov-

ernment research agenda will complement these efforts by industry and academia. USDA's Research, Education, and Economics (REE) mission area worked with USDA's Office of Food Safety, other government food safety agencies, and stakeholders to develop the unified research agenda. The unified agenda prioritizes research needs and maximizes use of available resources.

ENHANCE PUBLIC EDUCATION EFFORTS

Because everyone has a responsibility for food safety, educating the public about this responsibility is a crucial element in FSIS' food safety mission. All food preparers, from consumers to food service employees, must know and understand basic safe food-handling practices. These efforts must be broad enough to ensure that no segment of the public is uninformed about safe food handling practices, yet at the same time, target various segments of the population to positively influence those behaviors that pose the greatest potential risk. Communicating with the public about food safety must be accomplished in a manner that is easily understandable so that it is useful to every segment of the population. Thus, FSIS has considered innovative and collaborative methods for delivering the food safety message.

The Food Safety Mobile

One such innovative way of spreading the food safety message is USDA's Food Safety Mobile, which was introduced in March 2003. This eye-catching "food safety educator-on-wheels" brings food safety information to consumers and builds on our partnerships in communities across the country. Through the Food Safety Mobile, FSIS is sharing its food safety message with the general public as well as culturally diverse and underserved populations and those with the highest risk from foodborne illnesses. From March to November 2003, the Mobile traveled over 24,000 miles and participated in 87 events in 64 cities across the country. These events ranged from county fairs and grocery store demonstrations, to the Taste of Minnesota and the Philadelphia Thanksgiving Day Parade. FSIS used these opportunities to provide information and publications on food safety to approximately 179,000 people face-to-face at Mobile events. FSIS estimates 64.4 million media impressions from the Mobile, and that does not include internet exposure.

Educational Campaign

FSIS has also been conducting an educational campaign through public events and media interviews with national and regional media organizations in order to reach more of the population with important public health messages. Recent events were held in Houston, Philadelphia, Portland, San Francisco, Miami, and the Flathead Reservation in Montana. National television interviews have been conducted with major television networks, including Fox News, Telemundo and Univision. National celebrities, such as former Miss America Heather Whitestone McCallum, pop music legend Olivia Newton-John, and country singer Wynonna Judd, have also been recruited to help FSIS reach even larger audiences with food safety messages through special events and the filming of Public Service Announcements (PSA). The results have been impressive. The Heather Whitestone McCallum PSA has aired 14,448 times since September 2003. This PSA ranked in the top 3 percent of all PSA's shown during the month of January 2004 along with PSA's by the American Red Cross, the Federal Emergency Management Agency (FEMA), and the Department of Homeland Security (DHS).

USDA's Meat and Poultry Hotline

USDA's Meat and Poultry Hotline is an additional tool that FSIS uses to share its food safety message. The Hotline handled over 98,000 calls and 80 media and information multiplier calls during fiscal year 2003. Calls included requests from newspapers, magazines, radio, television, and book authors, and included live interviews with radio and television stations. The Hotline also provides recorded information and live assistance for our Spanish-speaking callers. Additionally, the Hotline was a key resource for keeping the public informed about the BSE situation in Washington and has handled approximately 4,000 calls and 1,000 emails concerning BSE since December 23, 2003.

PROTECT MEAT, POULTRY, AND EGG PRODUCTS AGAINST INTENTIONAL CONTAMINATION

In the aftermath of September 11, 2001, there is recognition that threats to the well being of the Nation's citizens can come in the form of terrorist attacks, including the intentional contamination of food. With a strong food safety infrastructure already in place, FSIS has been focusing on fortifying existing programs and improving internal and external lines of communication. By partnering with other agencies, including CDC, FDA, USDA's Agricultural Research Service (ARS), DHS,

APHIS, the Environmental Protection Agency (EPA), as well as international partners such as the Canadian and Mexican governments' food inspection agencies, and State and local health agencies, FSIS is in a pivotal position to share information and to strengthen critical infrastructure protection activities concerning food from farm to table.

FSIS Office of Food Security and Emergency Preparedness

To date, FSIS has undertaken a number of initiatives to protect meat, poultry, and egg products from the potential of a terrorist attack. Immediately following September 11, 2001, FSIS established the Food Biosecurity Action Team (F-BAT). The charge of F-BAT was to coordinate all activities related to biosecurity, counter-terrorism, and emergency preparedness within FSIS. These activities are coordinated with USDA's Homeland Security Council, other government agencies, and industry. Currently, FSIS' newly created Office of Food Security and Emergency Preparedness (OFSEP) has assumed the responsibilities of F-BAT and serves as the centralized office within FSIS for food security issues.

OFSEP interacts closely with USDA's Homeland Security Council and represents the agency on all food security matters throughout the Federal Government, as well as in State and local activities. The Office's mission is to lead in the development of the agency's infrastructure and capacity to prepare for, prevent, and respond to, deliberate attacks or other threats to the U.S. food supply. As the lead coordinator and primary point of contact on all food security and emergency preparedness activities within FSIS, OFSEP focuses primarily on:

—Emergency preparedness and response;
—Federal/State/Industry Relations;
—Continuity of operations (COOP);
—Scientific expertise in chemical, biological, and radiological terrorism; and,
—Security clearance and safeguarding classified information.

To ensure coordination of these activities involves all program areas of the agency, OFSEP established a new standing advisory group, the Food Security Advisory Team (FSAT), comprised of representatives of the major program areas within FSIS, to provide program-specific technical support.

Expanding Coordination with Federal, State, and Local Agencies

FSIS collaborates and coordinates closely with its State partners to ensure an effective prevention and response program. Some of the many state organizations FSIS works with include the Association of Food and Drug Officials (AFDO); the Association of State and Territorial Health Officials (ASTHO); and the National Association of State Departments of Agriculture (NASDA). Most recently, FSIS teamed with FDA in cosponsoring a joint meeting between ASTHO and NASDA, entitled "Homeland Security: Protecting Agriculture, the Food Supply, and Public Health—The Role of the States." The purpose of this meeting was to enhance collaboration between State public health and agriculture agencies and the Federal Government. Both the Secretary of Agriculture and the Secretary of Health and Human Services (HHS) were on hand for this joint meeting.

FSIS also works closely with the White House Homeland Security Council, DHS, FDA, and the USDA Homeland Security Staff to develop strategies to protect the food supply from an intentional attack. For example, FSIS, along with FDA and industry partners, is working with DHS to establish a new food information sharing and analysis activity for the food sector. This public/private partnership will aid in the protection of the critical food infrastructure by centralizing the information about threats, incidents, and vulnerabilities.

Consumer Homeland Security Education

Because everyone has a stake in a safe and secure food supply, FSIS published Food Safety and Food Security: What Consumers Need to Know in November 2003, as part of the agency's continuing effort to protect public health by preventing and responding to contamination of the food supply throughout the farm-to-table continuum. The brochure, developed by FSIS, is available in both English and Spanish. In a concise and easy-to-follow format, Food Safety and Food Security: What Consumers Need to Know, lays out comprehensive and practical information about safe food handling practices, foodborne illness, product recalls, keeping foods safe during an emergency and reporting suspected instances of food tampering. This publication is the latest in a series of food security guidelines issued by FSIS that includes FSIS Security Guidelines for Food Processors and FSIS Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry and Egg Products.

Ensuring the Safety of Imports

To further strengthen our import inspection program, we established a new position called the import surveillance liaison inspector, using funds provided in the fiscal year 2001 Homeland Security Supplemental Appropriations Act. These inspectors augment the current activities of traditional import inspectors at locations across the country. The import surveillance liaison inspectors conduct a broader range of surveillance activities, and they coordinate with other agencies, such as the APHIS, FDA, and the U.S. Customs and Border Protection within the DHS. Currently, 20 of these new inspectors are on board, and we anticipate more will be added.

Laboratories

Laboratories play a key role in our ability to quickly detect contamination of the food supply. FSIS has four ISO accredited laboratories—three regulatory laboratories that conduct testing on samples of meat, poultry and egg products, and a fourth laboratory that focuses on microbial outbreaks. FSIS has increased security at all of our laboratories. This includes instituting procedures to ensure proper chain of custody and other controls on all samples and materials received by the labs. The labs participate in the Electronic Laboratory Exchange Network (eLEXNET), which is a system designed to provide a secure network in which food safety labs at various levels of government can share test data on food samples.

Furthermore, FSIS laboratories have enhanced analytical capability for compounds of concern and developed surge capacity. Our four labs have expanded capability to test for non-traditional microbial, chemical and radiological threat agents. In addition, the Agency has also begun construction of a Bio Security Level 3 facility that will be able to conduct analyses on a larger range of potential bioterrorism agents.

FSIS is also represented on the interagency Laboratory Response Network and has worked to develop the Food Emergency Response Network (FERN) for potential foodborne contamination incidents. FERN was formed in 2002 and currently has about 61 members, including FSIS, FDA, and state labs. Participation is open to Federal, State, and local government labs that are capable of conducting food testing and forensic analysis for a wide variety of chemical, biological and radiological agents. FERN can help respond to national emergencies, including terrorist threats that might affect the food supply. In fiscal year 2005, FSIS plans to significantly expand its participation in FERN.

FISCAL YEAR 2005 BUDGET REQUEST

I appreciate having the opportunity to discuss a number of FSIS' accomplishments with you. Now I would like to present an overview of the fiscal year 2005 budget request for FSIS. Implementation of these budget initiatives is imperative to helping us attain FSIS' public health mission. In fiscal year 2005, FSIS is requesting a program level of $951.7 million, a net increase of about $61 million from the enacted level for fiscal year 2004. Under current law, we are requesting an appropriation of $838.7 million, with an additional $113 million in existing user fees.

Supporting FSIS' Basic Mission

The FSIS budget request for fiscal year 2005 supports the Agency's basic mission of providing continuous food safety inspection in each meat, poultry, and egg products establishment in the United States. The fiscal year 2005 budget includes $15.5 million in increases for mandatory pay raises in Federal and State programs. This includes annualization of the calendar year 2004 pay raise, as well as the anticipated calendar year 2005 pay raise.

The fiscal year 2005 budget request includes a $17.3 million increase for the full cost of in-plant inspection and enforcement of humane handling and slaughter. FSIS employee salary, benefits, and inspector travel between plants make up a large portion of the FSIS budget and have a serious affect on our ability to staff plants if not fully funded. Thus, FSIS requires a $12.3 million increase to avoid detrimental employment restrictions within the agency, which would result if unavoidable cost increases are not fully funded and must be absorbed. An additional $5 million is requested so that FSIS' inspection workforce can continue its strict enforcement of regulations for humane slaughter and handling of livestock, a top priority at FSIS.

New Initiatives

The fiscal year 2005 request includes a $33.6 million increase for new initiatives that support the Department's goals for FSIS.

BSE Surveillance

First, the fiscal year 2005 budget request includes an increase of $3 million for BSE surveillance. FSIS' BSE inspection program will add permanent BSE control measures in fiscal year 2005, which include: increased in-plant verification of slaughter plant designs for controlling specified risk materials (SRMs), overtime inspection, and travel for Veterinary Medical Officers to test non-ambulatory disabled livestock when they arrive at small slaughter plants that do not have a resident veterinarian. FSIS will also perform about 60,000 screening tests in fiscal year 2005 at processing plants that use advanced meat recovery (AMR) equipment, to ensure that SRMs do not enter the food supply.

Food and Agriculture Defense Initiative

The fiscal year 2005 budget also requests a $23.5 million increase to support a food and agriculture defense initiative in partnership with USDA, HHS, and DHS. Food contamination and animal and plant diseases and infestations can have catastrophic effects on human health and the economy. The three Federal Departments involved are working together to create a comprehensive food and agriculture policy that will improve the government's ability to respond to the dangers of disease, pests and poisons, whether natural or intentionally introduced. Our food and agriculture defense initiative has five components:

—Biosurveillance;
—The Food Emergency Response Network;
—Data systems to support the Food Emergency Response Network;
—Enhancing FSIS laboratory capabilities; and
—Follow-up bio-security training.

First, the food and agriculture defense initiative will allow FSIS to participate in an interagency biosurveillance initiative that would improve the Federal Government's ability to rapidly identify and characterize a potential bioterrorist attack. Funding this initiative will improve Federal surveillance capabilities and enable FSIS to integrate with DHS to compile FSIS surveillance information rapidly with threat information. This funding would also allow FSIS to focus its resources on the vulnerable products and processes identified during the agency's vulnerability assessments of imported and domestic products; increase regulatory sampling for three additional threat agents; add five Import Surveillance Liaison Inspectors, 30 program investigators for transportation, distribution, and retail surveillance, and two Public Health and Epidemiology Liaison Officers to our workforce; and establish a Foodborne Disease Surveillance Communication system to coordinate with DHS systems.

The second component of the food and agriculture defense initiative is the Food Emergency Response Network (FERN), which I discussed earlier. A nationwide laboratory system with sufficient capacity to meet the needs of anticipated emergences is integral to any bioterrorism surveillance and monitoring system. The goal is to establish 100 FERN laboratories, creating a network of Federal, State and local laboratories that FSIS could call upon to handle the numerous samples that would be required to be tested in the event of a terrorist attack on the meat, poultry or egg products supply. The fiscal year 2005 budget request would expand FERN to contract with State and local laboratories, and to establish five regional hubs and a National Operating Center to coordinate FERN's efforts and conduct training. In addition, FSIS would also fund the establishment of five to seven State laboratories for screening of microbiological agents, with more laboratories in the future, based on the availability of funds.

The third and fourth components of the food and agriculture defense initiative provide further support to FERN. The electronic laboratory exchange network (eLEXNET), which I mentioned previously, is a national, web-based, electronic data reporting system that allows analytical laboratories to rapidly report and exchange standardized data. The fiscal year 2005 budget request would provide funding needed to make eLEXNET available to additional FERN and other food-testing laboratories nationwide. In turn, the budget request would enhance FSIS' laboratory capabilities in order to detect new bioterror-associated agents, and to ensure FSIS' capability and capacity to perform the toxin and chemical testing that will be standardized across all FERN laboratories.

Because the realm of biosecurity is ever changing, FSIS must provide its workforce with the most up-to-date information necessary to ensure that meat, poultry, and egg products are protected from intentional contamination. Therefore, the final component of the food and agriculture defense initiative is follow-up biosecurity training of the workforce. This additional training is essential as part of the ongoing effort to protect the public by educating the workforce regarding the latest threat agents and countermeasures to those agents.

Training and Education

Training is a top priority at FSIS. Our inspection workforce is our greatest asset, and this is why FSIS is dedicated to establishing and maintaining a comprehensive and fully integrated training program. The agency is continuing its extensive training effort by requesting approximately $7.1 million, or an increase of 50 percent over fiscal year 2004, to train all new inspection personnel and to expand existing training programs in fiscal year 2005.

To ensure that newly hired inspection personnel receive the proper orientation and training to perform their jobs when they report to duty, FSIS is requesting approximately $4 million in fiscal year 2005. The agency has been criticized in the past for not immediately training all new employees. This initiative will provide the formal training needed to ensure that inspection procedures are performed consistently and appropriately under agency policies. This initiative will also enable FSIS to place 10 district trainers, in addition to five already funded in the agency's baseline, throughout the Nation, to orient and train FSIS employees.

Last year, FSIS began retooling and expanding its existing training programs by incorporating a public health focus and integrating scientific and technical principles with training on technical and regulatory approaches to inspection. Through the $3.1 million requested by FSIS in fiscal year 2005, the agency would continue to provide Food Safety Regulatory Essentials (FSRE) training to field employees, including food inspectors, CSOs, Inspectors-in-Charge, and Compliance Officers. The agency will offer the training regionally to accommodate inspection staff. Additional computer-based-training will be provided to implement the training, and will be catered to the inspection personnel's specific food safety responsibilities.

User Fee Proposal

Under current law, in 2005 FSIS estimates it will collect $113 million in annual user fees to recover the costs of overtime, holiday, and voluntary inspection. FSIS' fiscal year 2005 budget includes a legislative proposal to recover the costs of providing inspection services beyond an approved 8-hour primary shift. The proposal was submitted to Congress last August. If enacted, the level of appropriated funds needed would be reduced by an estimated $124 million, making the FSIS budget request $714.7 million. This will result in significant savings for the American taxpayer.

CLOSING

The goals and initiatives that FSIS has laid out as its vision represent a monumental task. But let me assure you; this is a task that we are ready and willing to take on. I believe that with the appropriate support, FSIS will be able to achieve its public health vision and strengthen the safety of meat, poultry, and egg products.

Mr. Chairman, this concludes my prepared statement. Thank you for your continued support. Thank you also for the opportunity to submit testimony to the Subcommittee on how FSIS is working with Congress and other partners to achieve its public health vision.

ADDITIONAL COMMITTEE QUESTIONS

Senator BENNETT. Thank you very much for your testimony.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR ROBERT F. BENNETT

BSE

Question. On March 15, 2004, the Department of Agriculture announced details for an expanded surveillance effort for BSE. The release also stated that $70 million is being transferred from the Commodity Credit Corporation (CCC) to test cattle in the high risk population. According to the announcement, the $70 million will allow testing of 268,000 animals. Using the Department estimate, testing all animals destined for export could cost at or near $1 billion.

In your opinion, do you believe testing 100 percent of the export market is possible? Also, any additional comments or updates in regard to the cost of animal testing would be appreciated.

Answer. Although it is logistically possible to test 100 percent of the cattle slaughtered in the United States every year, USDA does not recommend following this

course of action. Testing predominantly young, healthy animals beyond the bounds of a scientific surveillance plan would create a false sense of security for consumers and could lead to either a tiered system (testing for exports but not for domestic consumption) or, more probably, testing all cattle slaughtered.

USDA's targeted surveillance program is designed to identify the presence of BSE in the U.S. cattle population if it exists. We understand that some in industry have suggested blanket-testing all animals presented at slaughter as a means of providing "BSE-screened products" and easing trade barriers. However, it is our contention that current barriers against U.S. beef are scientifically unwarranted, and we continue working at the highest levels to reopen foreign markets for U.S. producers.

We must clarify that surveillance testing for BSE—especially if it is performed on clinically normal animals at slaughter—is not an efficient risk mitigation measure for protecting public health. USDA is confident that the removal of specified risk materials, along with other measures such as feed practices regulated by the Food and Drug Administration address the potential health risk of BSE.

USDA's BSE surveillance program has always focused testing efforts on those animals that fall into the highest-risk category for the disease. These include cattle exhibiting signs of neurologic disease; condemned at slaughter for neurologic reasons; testing negative for rabies and submitted to public health laboratories and teaching hospitals; and appearing non-ambulatory (including those exhibiting general weakness severe enough to make it difficult but not impossible to stand), also known as "downer cattle." We also sample adult cattle that have died for unexplained reasons.

We estimate that approximately 35 million cattle are slaughtered in the United States annually. If each one of these animals were to be tested, and we included the cost of the test kit, sample collection, shipping and handling, laboratory processing and support, training, equipment, and other associated fees, USDA estimates that the total cost would be between $175 and $200 per animal. Thus, the total cost for testing every animal slaughtered could reach as high as $6 to $7 billion per year.

Question. The livestock industry and Department of Agriculture are working toward reopening export markets in Japan, Mexico, and other exporting countries. The controversy arises over testing each animal and whether or not animals under the age of 30 months should be tested.

Do you believe each animal, including those under 30 months of age, should be tested prior to export?

Answer. USDA's targeted surveillance program is designed to identify the presence of BSE in the U.S. cattle population if it exists. We do not agree that blanket-testing all animals prior to export, including those under 30 months of age, is a scientifically sound approach to disease surveillance.

USDA's BSE surveillance program has always focused testing efforts on those animals that fall into the highest-risk category for the disease. These include cattle exhibiting signs of neurologic disease; condemned at slaughter for neurologic reasons; testing negative for rabies and submitted to public health laboratories and teaching hospitals; and appearing non-ambulatory (including those exhibiting general weakness severe enough to make it difficult but not impossible to stand), also known as "downer cattle." We also sample adult cattle that have died for unexplained reasons.

AVIAN INFLUENZA

Question. The Administration's fiscal year 2005 Budget request includes an increase in funding of $11.783 million to address Low Pathogenic Avian Influenza (LPAI) in live bird markets.

Can you update the Committee in regard to ongoing action related to avian influenza and explain how the Department would utilize the additional funding?

Answer. APHIS has been working to establish a national LPAI program and incorporate it into the National Poultry Improvement Plan (NPIP). The national LPAI program will be discussed and hopefully adopted at the NPIP meeting in July 2004. The program has drafted a Uniform Methods and Rules (UM&R) for the live bird marketing portion of the program and the subcommittee of the U.S. Animal Health Association is currently reviewing the draft to obtain their recommendations for program improvement.

APHIS would utilize the additional funding for cooperative agreements with states that will support the LPAI prevention and control program; for indemnities; for additional field personnel, equipment, and other resources necessary to assist states with long-term prevention and control; for educational materials and training for recognition of avian influenza and for biosecurity practices to protect against the disease; for development and administration of vaccine to support industry when infected with LPAI; and for reagents and other laboratory support to incorporate the commercial program through the National Poultry Improvement Program (NPIP).

This program is currently testing poultry breeder flocks and will continue to expand its activities until all segments of the commercial industry are monitored and certified as avian influenza clean.

Question. With the discovery of avian influenza, a number of countries have banned poultry imports from the United States.

Can you provide the Committee with an update on poultry export markets and exactly what actions USDA is taking to reopen these markets?

Answer. The USDA is currently working with countries that have imposed bans on taking the necessary actions to remove the bans on exports and reopen all poultry markets. Our actions include: depopulating positive testing flocks, cleaning and disinfecting those flocks, providing additional surveillance activities to ensure that all positive have been removed, and responding to inquiries and questionnaires to prove that areas are free of avian influenza and trade bans can be removed.

On April 6, the Canadian Food Inspection Agency (CFIA) recognized the United States as free of highly pathogenic avian influenza (HPAI) and lifted all HPAI-related importation bans on U.S.-origin birds, poultry, and poultry products. Other countries including Armenia, Macedonia, and Serbia have removed their bans and have allowed exports to enter their country. Several other countries including: Chile, Czech Republic, Hungary, Israel, Poland, and Taiwan have reduced their restrictions to allow poultry exports from all states except for Texas.

CHILDHOOD OBESITY

Question. Childhood obesity is a growing health concern for many Americans. The Department of Agriculture has and continues to conduct research to further understand the factors that contribute to obesity.

Can you update the Committee in regard to actions that the Department is taking to inform consumers and to combat obesity?

Answer. The Department is making a substantial commitment to promoting healthy weight through nutrition education and promotion. In the Food, Nutrition, and Consumer Services (FNCS) mission area, the Food and Nutrition Service (FNS) nutrition education efforts are targeted primarily to participants or potential participants in the nutrition assistance programs it administers, while the Center for Nutrition Policy and Promotion (CNPP) provides nutrition education and information for the general public. In addition, the Cooperative State Research, Education and Extension Service (CSREES) has a significant commitment to nutrition education, as well as the Agricultural Research Service and the Economic Research Service, who perform basic and applied research supporting this effort.

FNCS undertakes a range of ongoing activities each year to deliver nutrition education and promotion to program recipients; all of these include maintenance of proper weight as one component of a healthy lifestyle, including:

—*Integrating nutrition and physical activity promotion within and across the programs.*—The Eat Smart. Play Hard.™ campaign for children and their caregivers stresses the need to balance what you eat with how active you are, and Team Nutrition provides nutrition education for the Nation's schoolchildren. Materials such as brochures, activity sheets and posters, coordinated with nutrition curricula, are used to help children, their parents, and caregivers learn healthy eating and active living behaviors.

—*Reshaping nutrition education in the Food Stamp Program.*—To target activities that promote healthy weight. For example, we are developing new nutrition education materials that program staff can use to motivate low-income elderly people and women with children to improve their eating behaviors.

—*Developing new ways to support healthy weight through the WIC program.*—The Fit WIC project developed five intervention programs that WIC and other community agencies can implement to prevent overweight in young children. Educational packages such as Fathers Supporting Breastfeeding are used in WIC clinics to support breastfeeding. Breastfed babies are less likely to become overweight as they grow, and mothers who breastfeed may return to pre-pregnancy weight more easily.

—*Promoting healthy school nutrition environments.*—Unhealthful beverage and food choices at school can undermine children's ability to learn and practice healthy eating. We developed and are distributing the Changing the Scene action kit to help local schools and communities to support healthier eating and active living behaviors.

—*Promoting increased fruit and vegetable intake.*—Through partnerships with other Federal Agencies and the National 5-A-Day Program. For example, we worked together to develop the Fruits and Vegetables Galore-Helping Kids Eat More tool kit, which helps foodservice professionals with planning, preparation,

and promotion strategies to encourage the children they serve to consume more fruit and vegetables. For fiscal year 2005, the President's Budget proposes several initiatives to enhance these efforts to better address obesity and promote healthy weight. These include:

—The budget requests $20 million, a $5 million increase, to enhance WIC breastfeeding promotion efforts through peer counseling. The use of breastfeeding peer counselors has proven to be an effective method of increasing initiation and duration of breastfeeding, and breastfed babies are more likely to maintain a healthy weight as they grow.

—The budget requests $5 million to initiate a new series of WIC Childhood Obesity Prevention Projects, which build on the success of the Fit WIC projects to work in partnership with States on innovative strategies to use WIC to prevent and reduce childhood obesity through enhanced nutrition and education, physical activity promotion, and environmental efforts. Ongoing funding for such projects is critical to ensuring continuous improvement in this area.

—It requests $2.5 million to expand the Eat Smart. Play Hard.™ Campaign and establish a cross-program nutrition framework to help ensure a comprehensive, integrated approach to nutrition education in all FNS nutrition assistance programs.

—The budget includes $1 million for the Center for Nutrition Policy and Promotion (CNPP) plans to build on previous work to implement the consumer messages developed and pilot tested with 20- to 40- year-old women, especially low-income women, to help consumers aim for a healthy weight.

—The budget requests as additional $655,000 to complete the development of the 6th edition of the Dietary Guidelines for Americans, as well as an additional $1 million to update and promote the new food guidance system which will update the Food Guide Pyramid. CNPP also plans to develop obesity prevention materials based on the Dietary Guidelines and the new food guidance system, as well as promote the consumption of fresh fruit and vegetables. Plans include the development of print materials and interactive tools, such as the Interactive Healthy Eating Index, that direct dietary guidance to the individual to facilitate healthful behavior change.

INDEFINITE FUNDING IN THE FOOD STAMP ACT

Question. The Administration's fiscal year 2005 Budget includes a request for new legislative language to allow for indefinite funding authority for the Food Stamp Act.

Can you provide the Committee with an explanation of why this legislative language has been requested?

Answer. The indefinite authority proposal in this year's Food Stamp Program budget would provide such sums as necessary to fund program benefits and payments to States, in the last 4 months of the fiscal year if program needs exceed the anticipated level. It would ensure that sufficient resources will always be available to provide access to the program for all eligible persons who wish to participate. It can be difficult to estimate program needs or the size of an adequate contingency reserve, particularly when there are changes in the economy. With indefinite authority, if program costs should significantly exceed budget estimates, it would never be necessary to seek a supplementary appropriation or implement a benefit reduction. This proposal would bring the structure of this critical program in line with other major social welfare programs that already have indefinite authority.

QUESTIONS SUBMITTED BY SENATOR CHRISTOPHER S. BOND

GUIDELINES ON FAT CONSUMPTION

Question. There is a linear relationship between high transfatty acid and high saturated fat intake and chronic disease. We also know that the consumption of foods high in these two elements likely contribute to the statistics on obesity.

Does USDA intend to draft guidelines or standards for the consumption of these fats?

Answer. The 2005 Dietary Guidelines Advisory Committee (DGAC) is in the process of evaluating the most recent scientific evidence on fatty acids and health and is preparing to make science-based recommendations specifically for saturated and trans fatty acids consumption. At its most recent public meeting held on March 30 and 31, 2004, members of the Committee discussed the possibility of setting intake goals for both types of these fatty acids—saturated and trans—and also discussed the implications these proposed recommendations would have for the general public.

It is expected that the dietary fat recommendations will emphasize the reduction of current intake for saturated and trans fatty acids. The Committee is also expected to address the need for encouraging product reformulations by food manufacturers to reduce unhealthy fats in food products. It should be noted that on July 11, 2003, the Food and Drug Administration published a final rule requiring food manufacturers to list the amount of trans fatty acids on product nutrition labels by January 1, 2006. Some manufacturers have already responded to the rule by implementing the labeling requirement or by eliminating trans fatty acids from their products.

The Committee is continuing its deliberations on specific fatty acid recommendations. However, the final advisory report is expected to be submitted to USDA and HHS by June 30, 2004. The final science-based recommendations on saturated and trans fatty acids will be incorporated in the agency's education and communication efforts after completion of the DGAC report.

In an effort to help Americans reduce their risk of cardiovascular disease and improve their health, USDA's proposed new Food Guidance System, to be released in 2005, emphasizes consumption of oils instead of solid fats in the diet and differentiates between saturated and unsaturated fats. The guidance recommends that Americans choose fats mostly from foods higher in polyunsaturated or monounsaturated fat, and particularly Omega-3 fats such as those found in fish.

Question. Since not all oils are equally healthy, will USDA provide guidelines and or regulations to restaurants and other food manufacturers and—more importantly—provide them a roadmap to increasing the nutritional content and decrease trans and saturated fat levels of their products?

Answer. The 2005 Dietary Guidelines Advisory Committee (DGAC) is in the process of evaluating the most recent scientific evidence on fatty acids and health and is preparing to make science-based recommendations specifically for saturated and trans fatty acids consumption. The Committee is also expected to address the need for encouraging product reformulations by food manufacturers to reduce unhealthy fats in food products.

Additionally, researchers from the Agricultural Research Service are working with agricultural producers and the fats and oils industry to find alternative ingredients and develop oils such as canola and sunflower oils with higher levels of the fatty acids that may help reduce levels of low-density lipoproteins—or bad cholesterol—without reducing the high-density lipoproteins—or good cholesterol. Through Federal research and education efforts, these "heart-friendlier" oil products are expected to be utilized by the food industry, offering trans fatty acid-free products in the marketplace.

Question. Does USDA intend to provide specific guidelines and or regulations on the characteristics of healthy oils highlighting those oils that have low saturated fat and transfat profiles that can be used in most food manufacturing to improve overall health and nutrition of those foods?

Answer. The 2005 Dietary Guidelines Advisory Committee (DGAC) is in the process of evaluating the most recent scientific evidence on fatty acids and health and is preparing to make science-based recommendations specifically for saturated and trans fatty acids consumption. At its most recent public meeting held on March 30 and 31, 2004, members of the Committee discussed the possibility of setting intake goals for both types of these fatty acids and also discussed the implications these proposed recommendations would have for the general public. It is expected that the dietary fat recommendations will emphasize reduction in saturated fatty acids and trans fatty acids. The Committee is also expected to address healthy fats and provide intake recommendations on how consumers can incorporate "healthy" oils in their diets. The USDA will incorporate the recommendations from the DGAC into its education and communication efforts after completion of the DGAC report. The USDA will provide consumers with information on the most common sources for "healthy" oils to offer them healthy choices in selecting a balanced diet.

Question. Does USDA have this authority?

Answer. USDA has authority to provide consumers with information on the nutritional content of foods, including oils and common sources for "healthy" oils. USDA attempts to help consumers, producers and industry by offering information regarding healthy choices when selecting a balanced diet.

Question. How does USDA intend to incorporate the information it hopes to disseminate through the campaigns mentioned in Mr. Bost's testimony into USDA run food programs?

Answer. Nutrition promotion efforts such as the Eat Smart.Play Hard.™ campaign and Team Nutrition are designed specifically to be delivered through the Federal nutrition assistance programs. Materials are developed by the Food and Nutrition Service (FNS) and disseminated to State and local program partners through

the web and direct delivery. Program cooperators also order campaign materials through the Department of Commerce's National Technical Information Service (NTIS).

Most of the materials developed to date are designed for use in specific programs. Part of the requested $2.5 million increase for cross-program nutrition activities will support development of nutrition promotion materials that can be integrated into more than one program, maximizing the impact of limited nutrition education funding.

FNS and the Center on Nutrition Policy and Promotion (CNPP) also work closely together to ensure that program-based nutrition education activities are fully consistent with the Dietary Guidelines for Americans and the food guidance system intended to deliver the Guidelines to the general population. These agencies confer directly, and participate together in the Dietary Guidance Working Group, which reviews nutrition education materials to ensure their consistency with Federal nutrition policy and guidance. When the new Guidelines and food guidance system are finalized, FNS will review all of its nutrition education interventions to ensure that they are consistent with the updated guidance, and make any needed changes.

SOYBEAN RUST

Question. In part due to a short U.S. soybean crop in 2003, the U.S. livestock industry is expected to import a larger amount of soybean meal this year than in the recent past. The usual source for U.S. soymeal imports is Brazil, which experienced the arrival of Asian soybean rust a few years ago. Since Asian soybean rust has not yet arrived in the United States, it is important that we do everything we can to delay that arrival as long as possible.

When will APHIS make a decision about any additional quarantine steps for imported soybeans or soybean meal that it will impose, and will APHIS consult with the relevant stakeholder groups, such as the American Soybean Association and livestock groups, before making a final decision?

Answer. APHIS officials are looking closely at our country's importation of soybean seed, meal, and grain. Our analysis to date has shown that clean soybean seed and soybean meal—which is a heat-treated, processed product—is unlikely to pose any risk of introducing this disease. Historically, there has never been a documented instance of soybean rust spread through trade. Rather, it is spread naturally through airborne spore dispersal. We are currently conducting a risk assessment to study the viability of the pathogen. The preliminary results of the assessment indicate a very low risk, if any, of introducing this disease through imports. We posted our initial risk document on the APHIS' Web site and requested public comments. The comment period closed April 12, 2004.

We have been working very closely with the American Soybean Association and other stakeholders throughout our efforts to prevent and prepare for the introduction of soybean rust. Most recently, USDA officials participated in a soybean rust conference that was cooperatively organized by USDA, five pesticide companies, and the American Soybean Association. The primary goal of the conference was to disseminate to soybean farmers the knowledge, information, and techniques they will need to manage this pathogen when it reaches the continental United States. We are committed to continuing and expanding this outreach, including working with the livestock industry, in our efforts develop policies for preventing the human-assisted entry of the disease. We will ensure that any new regulations regarding soybean imports are based on the best available scientific information.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

COMBATING CHILDHOOD OBESITY

Question. Mr. Bost, both USDA and FDA have recently announced new efforts to combat the increasing problem of obesity. FDA announced the "Calories Count" program, and USDA has money in several programs, including WIC, to help battle this problem. However, for all of the government's efforts, all of the money being put into this effort pales in comparison to the food industry's billions of dollars worth of advertising.

How can the government successfully get its message out when, at first glance, its efforts appear to be dwarfed by the food industry? How do your agencies compete with that?

Answer. USDA has a strong partnership with the Department of Health and Human Services, including CDC and FDA, which helps ensure that the Federal investment to combat obesity is a collaborative effort with consistent messages to the

public. USDA plans to capitalize on the Federal infrastructure working with the vast network of State, county, and other local government agencies and groups to extend the reach of their messages and materials. USDA is participating in the creation of a new Food Guidance System which would be the cornerstone of other Federal nutrition assistance programs. USDA is also actively exploring options for partnerships and seeking opportunities to collaborate with other health organizations, advocacy and industry groups to help carry the Federal Government messages.

Question. Mr. Bost, the Senate report of the fiscal year 2004 Agriculture Appropriations bill encouraged the USDA to work with Share Our Strength and its Operation Frontline (as well as other innovative organizations) to improve eating habits and food budgeting skills of program participants. In view of growing concern about obesity and health, those objectives seem as valid as ever.

What progress can the Department report in response to this encouragement?

Answer. Share Our Strength SOS provided my office with a proposal for Operation Frontline to provide nutrition education to nutrition assistance program participants. I also met with Bill Shore, the Executive Director of SOS, to discuss it with him personally before it was sent to the Food and Nutrition Service for a more thorough review. In our discussion, I learned that the project shares many of the same goals as USDA's nutrition education efforts, and uses a model similar to that used by State agencies in providing nutrition education and promotion to Food Stamp recipients.

As you know, nearly all of the nutrition education funding provided to FNS must be used for grants to State agencies that operate the programs, often for specifically earmarked purposes. The Department's ability to provide direct funding for organizations such as SOS is thus highly constrained, and we were unable to offer a grant to support Operation Frontline in response to their proposal. However, I was pleased to learn more about their efforts, and value SOS as a non-profit sector partner in our shared effort to promote healthy eating and wise use of food resources among low-income people.

COMMODITY SUPPLEMENTAL FOOD PROGRAM FISCAL YEAR 2004 FUNDING

Question. The Commodity Supplemental Food Program was forced to cut nearly 30,000 participants in fiscal year 2004. The current budget flat lines program funding, but the carryover funding from the previous years is no longer available. It has been estimated that this will cause another 30,000 people taken off the roles—all senior citizens.

How do you propose people at the state level, who actually carry out these programs, deal with a cut this deep?

Answer. About 29,500 fewer caseload slots were assigned in 2004 than in 2003. However, the caseload of 536,196 allocated in 2004 exceeds actual participation in any month to date, including the peak participation of 526,955 achieved in September 2003. Thus, the caseload available in 2004 covered actual nationwide program participation.

In reference to the President's fiscal year 2005 budget request, the $98.335 million requested for the Commodity Supplemental Food Program (CSFP) equals Congress' fiscal year 2004 program appropriation, and is higher than the $94.991 million requested in the budgets for fiscal years 2002 through 2004. However, variables beyond the Administration's control have yielded significantly fluctuating levels of total program resources over the same period. These variables are the amounts that Congress appropriates and cash carryover from the previous year, which is determined primarily by the extent to which States utilize their assigned caseloads. Even though the fiscal year 2005 budget request includes an increase over the prior year's request, the anticipated lack of cash carryover would result in a projected participation decrease of 60,700 nationally.

The Department will pursue all means to minimize the impact of straight-line funding for the program. We also wish to point out that we are implementing major initiatives, including more extensive and varied Food Stamp Program outreach efforts, which address the nutritional needs of the population served by the CSFP. People eligible for the program should also be eligible to receive benefits under the Emergency Food Assistance Program and the Nutrition Services Incentive Program now administered by the Department of Health and Human Services. The Food and Nutrition Service will work closely with State agencies to help affected individuals meet their nutritional needs through these other Federal nutrition assistance programs.

FOOD GUIDE PYRAMID

Question. Mr. Bost, you mentioned in your statement that the FNS is currently working on updating the food guide pyramid. I understand that you have received a significant number of comments so far on your efforts.

How many comments has FNS received on the proposed food guide pyramid?

Answer. Last September, a Notice was published in the Federal Register requesting comments from all stakeholders on the proposed technical revisions to the current Food Guide Pyramid. USDA is using an open and transparent process to revise the science base and communications elements for the current Food Guidance System, the Food Guide Pyramid. This process resulted in 255 response letters with 1,101 separate comments from a broad array of nutrition professionals, health organizations, academic faculty, food industry organizations and the general public. To continue this transparent process, we have made these comments available for anyone to view on our website at http://www.usda.gov/cnpp/pyramid-update/index.html.

Question. Do you believe you will be able to make the June deadline for publication?

Answer. The report to the Secretaries of Agriculture and Health and Human Services from the Dietary Guidelines Advisory Committee is expected to be finalized by June 30, 2004. The scientific advisory report will be published in electronic format on the USDA and HHS websites. The two Departments will then jointly review and publish the revised Dietary Guidelines, which is anticipated to be released in January 2005. The revised Food Guidance System is scheduled to be released approximately a month later, in February 2005.

LOW-CARBOHYDRATE DIETS

Question. How is USDA working to take into consideration the various low-carbohydrate diets that have become so popular in this country?

Answer. USDA continues to rely on consensus science from authoritative bodies and reports such as the report from the Dietary Guidelines Advisory Committee, the National Academy of Sciences, and USDA's food consumption surveys. USDA's Agricultural Research Service has six nutrition research centers that continually explore timely nutrition issues. As new weight-loss diet trends emerge, USDA works in collaboration with HHS as well as reputable organizations such as the American Dietetic Association and the Society for Nutrition Education, to plan communications strategies to help guide the American public to make healthy food choices.

Question. Is USDA, NIH or CDC doing any research on the safety and validity of these diets?

Answer. USDA's research is focused on energy balance and nutrient adequacy to effect long-term health. For optimal nutrient adequacy, the research continues to look at the nutrition requirements that ensure a healthy life, maximum vigor and well being and reduced risk of chronic disease, not to study the comparative effects of weight-loss diets. Where many new diet programs capture the interest of the public and come and go, nutritional requirements remain constant regardless of any particular diet. Much of our Federal research includes the role of carbohydrates, proteins, and fats and other nutrients play in a healthy diet.

NATIONAL ORGANIC STANDARDS BOARD

Question. Mr. Hawks, the Organic Foods Production Act is very clear that the NOSB should be able to hire their own Executive Director, and that that person should report to the NOSB directly. Is the job announcement published by USDA intended to meet the requirements of the statute in this regard?

Answer. AMS intends to meet the requirements of the Organic Foods Production Act (OFPA) which provides that the Board shall have a staff director.

The General Provisions of the Consolidated Appropriations Act, 2004, (Title VII) limit the Department's spending authority to "not more than $1.8 million for all advisory committees within USDA. Of this total, AMS has been allotted $90,000 for the National Organic Standards Board. This means that AMS can spend up to $90,000 of the funds appropriated for Organic Standards on the expenses of the NOSB. The Organic Foods Production Act requires that Board members be reimbursed for their travel expenses, including per diem. AMS cannot transfer appropriated funds to the Board to hire its own staff, nor do we have the authority to hire or contract for an employee who is not responsible to AMS.

Consequently, AMS recently filled an Advisory Board Specialist position. All of the specialist's time is dedicated to NOSB support under the direction of the National Organic Program (NOP) Manager. A complete description of the Advisory Board Specialist's duties will be provided for the record.

The increased funding provided by Congress in fiscal year 2004 will enable the Department to hire additional staff which will further increase the program's quantity and timeliness of service.

[The information follows:]

Advisory Board Specialist Responsibilities:

—Bi-annual re-establishment of the NOSB Charter
—Development and publication of news releases and Federal Register notices seeking nominees for NOSB membership
—Preparation of nominations packages and supporting documents for NOSB appointments
—Development and publication of news releases and Federal Register notices alerting the public to NOSB meetings
—Arranging public meetings; travel, hotel and meeting accommodations, and contracting for Court Reporters and Audio Visual Equipment
—Arranging guest speakers at NOSB meetings
—Reimbursing NOSB members for travel expenses in accordance with Federal travel regulations
—Development, maintenance, and administration of an NOSB website
—Reporting on Board activities
—Arranging and participating in NOSB committee conference call meetings
—Developing and publishing rulemaking actions to implement NOSB recommendations
—Contracting with vendors for Technical Advisory Panel (TAP) review of petitioned materials
—Reviewing petitions for compliance with OFPA, its implementing regulations, and the petition procedures
—Communicating with petitioners and the TAP vendors
—Identifying program needs for which the NOSB can provide advice
—Reviewing the work of the NOSB for completeness, accuracy, and compliance with OFPA, its implementing regulations, and the requirements of other Federal entities
—Performing all activities required for compliance with FACA
—Representing USDA at all meetings of the NOSB and its committees

Question. I understand that AMS has contracted with the American National Standards Institute to review the National Organic Program. Will the ANSI effort be a one-time audit or ongoing oversight panel, which is what was envisioned by the statute and the organic community. If the ANSI effort is a one-time review, what steps, if any, are being taken to create an ongoing Peer Review Panel, to oversee the accreditation activities of the National Organic Program?

Answer. We are in the process of completing an initial peer review of the NOP and hope to complete that review later this fiscal year. After this review is completed, we will make the results public and invite members of industry and the Board to work with us to develop a process for ongoing Peer Reviews of the NOP.

Question. Could you please provide the Committee with a list of the policy recommendations made by the NOSB since passage of the final organic rule, and what action has been taken by the Department in response to those recommendations?

Answer. The information is submitted for the record.

NOSB NON-MATERIALS RECOMMENDATIONS SINCE MARCH 2000

NOSB Recommendations	AMS Response
June 2001: Recommended regulations pertaining to labels with principal display panel, ingredient deck and information panel all on a single labeling panel.	The recommendation is covered by existing standards. Should AMS determine that there are problems with application of the standards; AMS will engage in rulemaking to clarify the requirements.
June 2001: Recommended Peer Review Panel procedures for review of accreditation program.	Review of AMS' accreditation program could not begin until after certifying agents were accredited. AMS has contracted with the American National Standards Institute for review of AMS' accreditation program. The review is underway.
June 2001: Recommended technical corrections to the final rule	AMS has acted on several of the recommended corrections and AMS is still working with the NOSB on others AMS will soon take action on the remainder.

NOSB NON-MATERIALS RECOMMENDATIONS SINCE MARCH 2000—Continued

NOSB Recommendations	AMS Response
September 2001: Recommended Apiculture Standards	The recommendation is covered by existing standards. Should AMS determine that there are problems with application of the standards; AMS will engage in rulemaking to clarify the requirements.
September 2001: Recommended guidance for preservatives used in vaccines.	The recommendation did not need AMS action beyond acceptance and posting on the Web. The recommendation is posted on the Web.[1]
October 2001: Recommendations on Aquatic Animals	AMS accepted the recommendations. The recommendations are posted on the Web.[1]
October 2001: Recommendations on Pasture	The recommendation is covered by existing standards. Should AMS determine that there are problems with application of the standards; AMS will engage in rulemaking to clarify the requirements.
October 2001: Recommendation, Principles of Organic Production and Handling.	The recommendation did not need AMS action beyond acceptance posting on the Web. The recommendation is posted on the Web.[1]
October 2001: Recommended procedures for amending the National List.	AMS follows the Federal Rulemaking procedures for amending regulations.
October 2001: Recommended Greenhouse Standards	The recommendation is covered by existing standards. Should AMS determine that there are problems with application of the standards; AMS will engage in rulemaking to clarify the requirements.
October 2001: Recommended Mushroom Standards	The recommendation is covered by existing standards. Should AMS determine that there are problems with application of the standards; AMS will engage in rulemaking to clarify the requirements.
October 2001: Recommended removing handlers from the $5,000 exemption.	AMS has not accepted the recommendation because it would violate the Organic Foods Production Act.
October 2001: Recommended adding ''certified'' in front of ''distributor'' in 3 places.	AMS has not accepted the recommendation because distributors are not required to be certified.
May 2002: Recommended guidelines for determining whether a processing technology shall be reviewed by the NOSB.	The recommendation is posted on the Web.[1] When AMS further defines what materials are subject to NOSB review, it may take further action on the technology recommendation.
May 2002: Recommended guidelines for US/EU equivalency	AMS has considered all points within this recommendation. USDA and USTR are in equivalency negotiations with the EU.
May 2002: Recommended that certifying agents use the Organic Farm Plan documents developed under an AMS cooperative agreement.	AMS fully supports the recommendation. The recommendation did not need AMS action beyond acceptance and posting on the Web. The recommendation is posted on the Web.[1]
May 2002: Recommended that certifying agents use the Organic Handling Plan documents developed under an AMS cooperative agreement.	AMS fully supports the recommendation. The recommendation did not need AMS action beyond acceptance and posting on the Web. The recommendation is posted on the Web.[1]
May 2002: Recommended clarification on ''access to the outdoors'' for poultry.	AMS accepted the recommendation and used it to develop an ''access to the outdoors'' policy statement for livestock which is posted on the Web.[1]

NOSB NON-MATERIALS RECOMMENDATIONS SINCE MARCH 2000—Continued

NOSB Recommendations	AMS Response
May 2002: Recommended a handling operation ingredient affidavit as guidance to handlers and certifying agents.	The recommendation did not need AMS action beyond acceptance and posting on the Web. The recommendation is posted on the Web.[1]
May 2002: Recommended clarification for section 205.606 relative to commercially available.	AMS is working with the NOSB on this issue. The NOSB is scheduled to provide a new recommendation on section 205.606 at its April 2004 meeting.
May 2002: Recommended clarification regarding planting stock for perennial crops grown as annual crops.	The recommendation did not need AMS action beyond acceptance and posting on the Web. The recommendation is posted on the Web.[1]
May 2002: Recommended guidance on transitional products	The recommendation is outside the National Organic Standards. AMS will take no action beyond posting the recommendation on the Web.[1]
May 2002: Recommended compost production methods beyond those specifically addressed in the NOP. The recommendation is intended as guidance.	AMS is working with the chair of the NOSB Compost Task Force on this issue. Specifically, AMS has requested scientific justification for the recommendations. AMS is concerned about the potential for human pathogens in the compost.
October 2002: Recommended regulation changes for origin of livestock; dairy animals.	The Organic Trade Association (OTA) filed its own recommendations relative to dairy animal replacement at the October 2002 NOSB meeting. The OTA and NOSB recommendations differ substantially. AMS is reviewing this issue.
May 2003: Approved a new recommendation on origin of dairy animals.	The Organic Trade Association (OTA) filed its own recommendations relative to dairy animal replacement at the October 2002 NOSB meeting. The OTA and NOSB recommendations differ substantially. AMS is reviewing this issue.
October 2002: Recommended criteria for certification of grower groups	AMS is reviewing this issue.
May 2003: Recommended publication of clarification management of breeder stock.	AMS is reviewing this issue.
May 2003: Recommended regulation change on chlorine contacting organic food.	AMS is working on a rulemaking docket that will address this recommendation.

[1] Website: http://www.ams.usda.gov/nop/indexIE.htm.

BEAVER CONTROL

Question. How does APHIS/Wildlife Services plan to uphold their cooperative responsibility with the Wisconsin Department of Natural Resources to provide beaver damage management activities that are being requested of them to restore trout streams that have been damaged by beavers?

Answer. APHIS/Wildlife Services (WS) cooperates with the Wisconsin Department of Natural Resources (WDNR) to conduct beaver damage management on high quality trout streams in Wisconsin. Beaver dam building activities can greatly alter the natural flow of a trout stream, destroying its ability to support trout. Beaver dams and the impoundments they create cause decreased water flow, water warming, and increased siltation. They also pose a barrier to trout, interfering with spawning. One component of the WS trout habitat protection program is to maintain select trout streams in free flowing, natural condition in order to improve or restore trout habitat and protect habitat improvement structures. The fiscal year 2005 budget will continue to fund these programs at current levels.

Question. Beaver damage to roads, bridges, crops, forests and property are also increasing in Wisconsin resulting in an increasing number of requests to Wildlife Services for assistance. The State of Wisconsin, some counties and some townships

provide cooperative funding to Wildlife Services for their assistance with beaver damage problems.

How does Wildlife Services plan to fulfill their cooperative responsibilities in responding to Wisconsin citizens' requests for beaver damage assistance?

Answer. APHIS/Wildlife Services (WS) cooperates with a number of northern Wisconsin county highway and forestry departments, and numerous local township road departments, to provide beaver damage management services for the protection of roads and road structures, and forestry resources. The fiscal year 2005 budget will continue to fund these programs at current levels.

BOVINE SPONGIFORM ENCEPHALOPATHY RECALL

Question. Dr. Murano, during the BSE scare, USDA announced that approximately 38,000 pounds of beef were recalled, after originally stating that the recall was only 10,400 pounds. Over the course of the following few weeks, we read stories about consumers who feared that they ate the contaminated meat because they were never informed that they purchased a part of the recalled amount, because proprietary information, including sales and distribution records, is kept secret during a voluntary recall. Further, there was a 3 week delay between the time the recall was announced and the time retailers found out about it.

How much of the recalled beef was actually found?

Answer. FSIS field personnel worked cooperatively with other Federal and State partners to conduct recall effectiveness checks on 100 percent of the establishments that sold or distributed the product associated with the recall. FSIS is confident that the product was quickly removed from the marketplace. FSIS determined that the recalling firm and its customers made extensive efforts to retrieve and dispose of the recalled product.

FSIS announced the recall at 1:00 a.m. on December 24, 2003. Less than 18 hours later, over 325 locations—primarily grocery stores—had received notifications from their suppliers.

On February 9, 2004, FSIS issued an update to the recall stating that approximately 21,000 pounds of product had been returned. This estimate was developed in late January 2004 using information from the FSIS investigation, including recall effectiveness checks.

Question. How long did it take between the time USDA announced the recall and the time individual grocery stores found out they had part of the contaminated beef? Was the responsibility on the grocers to find out for themselves, or were they all informed by either their state governments or USDA?

Answer. FSIS announced the recall at 1:00 a.m. on December 24, 2003. FSIS issued a press release that was distributed nationally. Simultaneously, its recall management division began collecting distribution information from the establishments that slaughtered and processed meat from the affected animal. Less than 18 hours later, over 325 locations—primarily grocery stores—had received notifications from their suppliers. It is the responsibility of the recalling company to notify its customers, including grocers, that they had received recalled product. FSIS then conducted effectiveness checks on the recall to confirm that the responsibilities of the recalling firm were met.

Question. If USDA had the authority to initiate mandatory recalls, do you think consumers would have found out more quickly? Why or why not?

Answer. No establishment has refused to comply with a recall requested by FSIS. Should they refuse, then FSIS has the legal authority to detain and/or seize meat, poultry and egg products in commerce. The current recall process is the quickest way to determine where the affected product has been distributed because companies are familiar with who their customers are and can notify them much more quickly than the Federal Government could. Public health would not likely be enhanced by the addition of mandatory recall authority because the Agency already has the means to remove product quickly from commerce.

Question. After all of the dust has settled, is USDA looking again at its policy of not wanting the authority for mandatory recalls?

Answer. Through effectiveness checks, public meetings and other means, FSIS is constantly reviewing and looking for ways to improve the recall process. In December 2002, FSIS held a public meeting to discuss improving the process for recalls of meat, poultry and egg products and to gather useful input on related topics. FSIS expects to issue a revised recall directive in fiscal year 2004 taking into account the comments it received at the public meeting. The directive will discuss how public notification of recalls is to take place and will provide information on the new risk-based system the agency will use for determining the scope of effectiveness checks.

SOUND SCIENCE

Question. Dr. Murano, in your testimony you stated that there was a significant drop in E.coli 157:H7 between 2002 and 2003, and credited this drop to reassessment of plants' HACCP plans and increased audits.

Were the same plants that were sampled in 2002 sampled in 2003? If not, how can you make a comparison between the two years? Unless the exact same plants were sampled, how can you be statistically certain that the plants sampled in 2002, but not sampled in 2003 have shown any improvement?

Answer. There are valid methods for analyzing a time series of data even though, as in this dataset, there are changes in the establishments being sampled from year to year. The analysis conducted by FSIS compares over 6,000 scheduled samples of ground beef production from fiscal year 2002 with over 6,000 samples of ground beef production from fiscal year 2003 and tests whether the populations are the same from year to year with respect to the presence of E. coli O157:H7. Statistical analysis was done using the Chi-square test to show the association between positive E. coli O157:H7 samples and laboratory method, season and year. A Poisson regression model was used to demonstrate the significant decline in percent positive samples from 2002 to 2003, after controlling for season and laboratory method. The conclusion is that the reduction in E. coli O157:H7 in raw ground beef from fiscal year 2002 to fiscal year 2003 was statistically significant.

On April 29, 2004, the Centers for Disease Control and Prevention, in its annual report on the incidence of infections from foodborne pathogens, noted a decline of 42 percent of illness caused by E.coli O157:H7 from 1996 to 2003. Most significantly, between 2002 and 2003, illnesses caused by E.coli O157:H7, typically associated with ground beef, dropped by 36 percent.

Question. Further, I have been informed that of the 58,000 samples collected for Salmonella in 2002, nearly 40,000 were collected from beef products, which have a lower rate of Salmonella than poultry products. It would appear that due to the high percentage of beef products sampled relative to other products, FSIS would be more likely to find a lower rate of positive Salmonella samples than if the percentages were weighted for equal comparison. Can you comment on this?

Answer. The agency has seven Salmonella performance standards for classes of raw product, and the highest number of samples is for raw ground beef because more establishments are subject to this standard than other standards.

On April 29, 2004, the Centers for Disease Control and Prevention, in its annual report on the incidence of infections from foodborne pathogens, noted that from 1996 to 2003, illnesses caused by Salmonella decreased 17 percent and Salmonella Typhimurium (typically associated with meat and poultry) decreased 38 percent.

Question. You mention the new need for new baseline studies in your statement. In fiscal year 2004 FSIS received funding for these activities.

What will you do, or are you currently doing, to ensure that these studies do not have some of the same problems as the previous studies, as outlined by the National Academy of Science? Will FSIS be using any of its fiscal year 2005 funding to continue conducting new baseline studies?

Answer. For the current baseline project, using the funds provided for fiscal year 2004, the agency developed a study protocol that was reviewed by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). FSIS modified the current plans based on NACMCF recommendations and will continue to seek comments from the National Advisory Committee on Microbiological Criteria for Foods on future baseline projects.

FSIS considers the fiscal year 2004 $1.65 million baseline initiative to be an addition to its base program and will continue to review funding needs for fiscal year 2005.

INSPECTOR TRAVEL

Question. Dr. Murano, it has been suggested that FSIS inspection personnel would benefit greatly from exposure and visits to slaughter facilities in different parts of the country, in order to compare differing methods of animal handling and slaughter practices to help them better enforce HMSA.

Would you consider making changes to your travel policy to provide an employee per diem for time spent visiting slaughter facilities, if done as part of an unrelated personal or business trip?

Answer. USDA is committed to strong enforcement of the HMSA. FSIS continually assesses its HMSA oversight and enforcement, primarily through the activities of the District Veterinary Medical Specialists (DVMSs). As methods are available to improve our HMSA efforts, the DVMSs develop strategies for incorporating them into the overall roles and responsibilities of the agency. Currently, DVMSs have au-

thority and opportunity to travel across district boundaries for humane activities when necessary.

SAUSAGE CASINGS

Question. Dr. Murano, this question involves a very specific issue related to food safety and sausage production in this time of concern about BSE. FSIS interim final regulations issued January 12 identify the distal ileum section of beef cattle small intestine as Specified Risk Material (SRM) in U.S. animals. In practice FSIS requires that the entire small intestine be removed and disposed of as inedible—presumably to ensure that the distal ileum is removed—even though I am told that the distal ileum can be definitively identified and removed without destroying the entire small intestine. This situation has the potential to cause harm to that segment of the sausage industry that relies on beef rounds as casing for their products.

Is there a way to ensure that the distal ileum SRM is completely removed, while still ensuring the safety and availability of beef rounds used as sausage casings?

Answer. FSIS is aware of the various methods for ensuring that the distal ileum is properly removed. FSIS specifically asked for comment in a Federal Register notice (January 12, 2004, Docket #03–025IF) on this issue and will be analyzing the comments. Meanwhile, FSIS also is aware that more than the distal ileum of the small intestine may demonstrate infectivity based on preliminary studies from the United Kingdom. FSIS is interested in gaining more information about this new development as FSIS analyzes the comments.

Question. I am told that current inventories for sausage casings could be exhausted within 2 months. Is it possible to provide further regulatory refinements to address this issue within that time frame?

Answer. Casings made from the small intestine of cattle slaughtered after January 12, 2004, are not currently allowed for human consumption. FSIS is aware of the demand for sausage casings made from the small intestine of cattle. However, in the interest of public health, FSIS will be analyzing the comments received on the interim final rule published on January 12, 2004, and further considering the potential ramifications of new findings that additional sections of the small intestine may demonstrate infectivity. FSIS will not change the restriction on the use of the small intestine in human food until after review of comments received.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

STATEMENT OF LESTER M. CRAWFORD, D.V.M., Ph.D.

Senator BENNETT. Dr. Crawford, we welcome you. I think this is your first time in this particular assignment and we look forward to hearing from you.

Mr. CRAWFORD. Thank you, Mr. Chairman and Senator Kohl. It is a pleasure for me to be here with my colleagues from USDA.

I want to thank you for the opportunity to discuss the Administration's fiscal year 2005 budget for the Food and Drug Administration.

As we approach our 100th birthday in 2006, our mission of promoting and protecting the public health has never been more vital. Likewise, the challenges and opportunities we face have never been greater.

This committee's generous support of FDA's mission over the past few years testifies to your recognition of the essential role our agency plays in the well being of all Americans.

The President's budget for proposal for fiscal year 2005 asks you to continue that support. It seeks $1.85 billion, $1.5 billion in budget authority and $350 million in user fees.

The budget authority increases total $138.9 and savings from administrative efficiencies and deferred facilities repairs and improvements of $30.1 million for a net increase of $108.8 million.

The President's budget request also asks you to build on your past support by increasing FDA funding in several priority areas. For Food Defense and Counterterrorism, we are seeking an increase of $65 million. Working with the White House Homeland Security Council, FDA and USDA have created a Joint Food Defense Budget that will strengthen our ability to protect the Nation's food and agriculture supply from threats whether deliberate or accidental.

$35 million is requested to establish a national laboratory network to test food samples. $15 million is requested for research to protect the food supply by such measures as better and faster tests to detect toxic agents in food. $7 million to increase FDA's food import examinations to nearly 100,000, six times the number we did in 2001. $3 million to increase our crisis management capabilities and $5 million to support the Administration's biosurveillance initiative.

For BSE, or mad cow disease, we are requesting an increase of $8.3 million.

Mr. Chairman, FDA is proud, and I think justifiably so, that we were able to trace and control all of the meat and bone meal associated with the BSE-infected cow discovered late last year in the Pacific Northwest. All of the rendering facilities we inspected as part of this one BSE case were in full compliance with our rules designed to create firewalls against BSE in this country. Nevertheless, we can and should do more.

We have already announced several measures to make those firewalls even stronger. With this increased funding, which if you approve it would bring our total BSE resources to $30 million, we will do three things. We will increase our State-funded BSE inspections by 2,500, we will add more than 900 risk-based BSE inspections and 600 targeted animal feed inspections, and we will conduct a total of 10,000 BSE inspections, 52 percent more than planned for the current year.

For our Medical Device Program, we are asking for an increase of $25 million. We are committed to ensuring that the Medical Device User Fee and Modernization Act is implemented in a manner that meets its performance goals and that ensure the strongest and most effective medical device review program possible under the law with available resources. We need this increase to meet the appropriations triggers required for the Agency to collect medical device user fees. With these resources, FDA will meet all of the performance goals by fiscal year 2008.

For the Center for Drug Evaluation and Research move to White Oak in Maryland, we are requesting an increase of $20.6 million in new budgetary authority and $10 million in user fees. We will use these resources to relocate the 1,700 review staff in the Center for Drug Evaluation and Research to the White Oak Campus.

For medical countermeasures, we seek an increase of $5 million. We are seeking this amount to bolster FDA's ability to help companies develop new medical countermeasures against terrorist attacks and to review those products quickly. FDA will use this increase to expedite the review of new drug applications, biologics license applications, generic drugs and over-the-counter medical product countermeasures.

For the pay increase we request an increase of $14.4 million. Fully 60 percent of our budget pays the salaries of FDA's dedicated expert employees. I need not emphasize here how important this money is for our ability to carry out our public health mission.

For administrative efficiencies, this budget request includes a reduction of $30 million. These funds will be used to partially fund the high priority initiatives I just mentioned as well as to support the goals of the President's Management Agenda.

Mr. Chairman, by focusing on the President's highest priorities for FDA, in some respects I have only scratched the surface of all that we do every day to protect the health of Americans.

An additional agency priority of particular interest to the Subcommittee, is lowering the rate of obesity, one of the most serious public health issues facing America today. We have just finished an FDA obesity working group which prescribes a number of recommendations and public input to reforming the food label to make it more amenable to the control of obesity, and also for demystifying some of the myths that now occur with respect to our food supply, not the least of which is confusion about carbohydrates and various classifications of carbohydrates.

PREPARED STATEMENT

I can list other additional program priorities, but in the interest of time I will submit my statement for the record and I appreciate very much the time accorded me.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF LESTER M. CRAWFORD

Introduction

Good morning. Mr. Chairman and distinguished members of the Subcommittee, I'm pleased to have the opportunity to speak with you today and present to you the Food and Drug Administration's fiscal year 2005 budget request. I am Dr. Lester M. Crawford, DVM, Ph.D. Acting Commissioner, Food and Drug Administration.

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our Nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

I'd like to begin by conveying my appreciation to the Subcommittee members and their staffs for providing FDA with several key increases in the fiscal year 2004 appropriation such as those funds for generic drugs, food defense, and medical device review. In a moment, I will elaborate on how we have spent or plan to spend those funds in the current year. I can assure you that funds appropriated in the current year and additional increases appropriated in fiscal year 2005 will continue to be spent wisely. The American people would be impressed if they really knew how much bang for their buck they get out of FDA.

I am fully aware of the difficult funding decisions all of you must face in the current session, but I want to remind you that marginal investments in FDA's programs can have such a positive ripple effect across all of your constituencies—from the consumer to the farmer to the manufacturer and beyond. FDA is working diligently to reduce administrative and IT costs in fiscal year 2004 and 2005. In fiscal year 2004, we offered $57 million in IT and administrative savings and we have again proposed another $23 million in administrative savings in fiscal year 2005, which we are realizing through efficient administrative resource management. We will continue to seek administrative resource savings in order to support our critical mission requirements.

Executive Summary

FDA makes substantial and meaningful differences in the lives of over 290 million Americans. I am extremely thankful for the professional dedication, creativity, and expertise of our staff. Through a combination of dedicated and skilled staff, new authorities of recently passed legislation, and the resources this Subcommittee provides us to carry out our mission, we will be in a better position to meet our challenges than ever before.

The Administration and Congress have an obligation to the American public to ensure that adequate and properly targeted resources are available for the continued success of the Agency and the success of the Federal Government's efforts to promote quality health care. The importance and complexity of FDA's work will only increase in the years to come as FDA continues to carry out its primary mission of protecting and promoting the public health. This means that while more medical products and therapies will be available to save and improve lives, FDA also must think critically and carefully about how it uses its resources to improve the public wellbeing. In guiding us through our new Strategic Action Plan that attempts to balance demands with limited resources, we will constantly follow the practice of "efficient risk management."

FDA's Strategic Plan

On August 20, 2003, FDA released a 5-Part Strategic Action Plan entitled "Protecting and Advancing America's Health: A Strategic Action Plan for the 21st Century." This is a dynamic and evolving document that outlines how the Agency is taking new steps to protect and advance America's public health. In response to various public health threats, the Agency developed a core set of consumer-focused goals that includes the following: helping consumers get truthful and non-misleading information about FDA regulated products; promoting quick access to new medical technologies that are safe and effective; improving patient and consumer safety; responding to the new challenges of bioterrorism and food defense, and building a stronger, science-based FDA. These goals were developed and refined in conjunction with a number of key healthcare stakeholders, and were based on important feedback from the consumer and patient communities. These are among the many critical challenges the Agency faces as it moves forward into the 21st century. I will first discuss these challenges and progress within our strategic planning effort, and then will discuss the specifics of FDA's 2005 budget request.

Efficient, Science-Based Risk Management

In fiscal year 2005, FDA will be charged with regulating over 150,000 drugs and devices, overseeing the development of almost 3,000 investigational new drugs, monitoring 125,000 domestic product establishments including over 10,000 firms involved in the animal drugs and feed process, reviewing and acting upon an estimated 13 million import line entries, and the list goes on and on. On top of this workload, we cover the full life cycle of nearly all food and medical products, and also interact on a daily basis with all facets of Federal and State governments, consumers, public and private institutions, and foreign entities. Our proposed budget includes the equivalent of 10,844 full-time employees, including reimbursables. The numbers speak for themselves and they explain why we must practice efficient, science based risk management in fulfilling our increasingly complex mission.

FDA's approach entails the use of the best scientific data, the development of quality standards, and the use of efficient systems and practices that provide clear and consistent decisions and communications to the American public and the regulated industries. This is achieved by employing principles and technologies that can reduce avoidable delays and cost in product approvals, overhauling and updating the way medical products are manufactured, implementing more effective strategies for food imports and food safety, and by implementing an enforcement strategy that combines clear communications to industry backed up by effective civil and criminal enforcement, FDA will achieve quicker access to safe and effective new products, and reduce public health risks without unnecessary costs. Over the past year, our work resulted in a wealth of success stories related to enforcement, new medical product development, imports and the safety of our food supply.

Our science based enforcement strategy is one based on clarity, science, leveraging resources with our enforcement partners in Justice, Homeland Security, and the states, and most importantly, deterrence. In fiscal year 2003, our efforts led to 341 arrests, 199 convictions, fines and restitutions of more than $800 million submitted to the U.S. Treasury (including a multimillion dollar settlement for health care fraud), 17 injunctions of firms/individuals, nearly 400 criminal cases opened, 25 seizures of violative products, and more than 500 Warning Letters. Additionally, we took action against drug counterfeiters, unscrupulous parties in the dietary supple-

ment industry, and those who spread misinformation or commit fraud via false labeling and advertising. We remain vigilant when necessary but hold the belief that our regulations and the enforcement of the regulations should be no more burdensome than necessary. In addition, FDA remains concerned about the public health implications of unapproved prescription drugs from entities seeking to profit by getting around U.S. legal standards for drug safety and effectiveness. Many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. Consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws. Although some purchasers of drugs from foreign sources may receive genuine product, others may unknowingly buy counterfeit copies that contain only inert ingredients, legitimate drugs that are outdated and have been diverted to unscrupulous resellers, or dangerous sub-potent or super-potent products that were improperly manufactured. The Agency has responded to the challenge of importation by employing a risk-based enforcement strategy to target our existing enforcement resources effectively in the face of multiple priorities, including homeland security, food safety and counterfeit drugs. However, the number of incoming packages, as it works today, already overwhelms the system, and this presents a significant ongoing challenge for the Agency. The Agency understands Congress' desire to address importation of drugs and appreciates their understanding of FDA's responsibility to uphold he current law.

New drug development is an extremely costly process. Today, we see cases where the cost of developing a novel drug may reach $800 million and take a decade to get from discovery to the marketplace. According to a Tufts University study, only 21.5 percent of new drugs successfully pass through the clinical phase and gain FDA approval. FDA must foster and encourage new product development by ensuring that its review and approval processes are efficient, transparent, consistent, and predictable. We need to ensure that biomedical innovation leads to the quick development of safe and effective medical products. As recently discussed in our report entitled "Innovation or Stagnation?—Challenge and Opportunity on the Critical Path to New Medical Products," FDA, together with academia, patient groups, industry, and other government agencies, must embark on an aggressive, collaborative research effort to create a new generation of performance standards and predictive tools that will provide better answers about the safety and effectiveness of investigational products, faster and with more certainty. This action promises not only to bring medical breakthroughs to patients more quickly, but to do so in ways that ensure greater understanding about how to maximize patient benefits and minimize their risks. This can be accomplished by developing quality systems for the Agency's review procedures, developing guidances in new areas of technology development, and continuing encouragement of quality improvement in the manufacturing sector.

We want to build on the past success of industry-supported programs such as the drug review process, which is funded by a combination of appropriated dollars and user fees defined by the Prescription Drug User Fee Act that will allow FDA to collect up to $284 million in fiscal year 2005. This program's support helped bring median approval times for standard new drug applications from 26.9 months in 1993 to 15.4 months in 2003. Increased funding for the past several years in the generic drugs program has allowed median approval times to drop from 39.7 months in 1993 to 17.3 in 2003, and an estimated time under 17 months with the fiscal year 2004 appropriation. We plan on this kind of support translating into similar success for the medical device review program with the help of budget authority and user fee dollars in fiscal year 2004 and beyond. Increased funding in fiscal year 2005 will allow the Agency to expedite the speed and quality of the medical device review process.

In the past year, highlights of our medical product review process include:

—in total, approved 483 new and generic drugs and biological products, including 21 New Molecular Entities with active ingredients never before marketed in the United States;

—approved 85 new drug applications;

—approved 373 generic drug applications;

—approved 25 biologic license applications;

—generic approvals included drugs for the treatment of hypertension and heart failure, the treatment and prevention of Cytomegalovirus Retinitis in AIDS and transplant patients; a treatment for major depressive disorder; and another for impetigo, an infection of the skin;

—accelerated approvals of a drug used for the treatment of pediatric patients with a type of myeloid leukemia—a rare, life-threatening form of cancer that ac-

counts for approximately 2 percent of all leukemias in children, and another for use in combination therapy for chronic Hepatitis C;

—over-the-counter drug approvals including Claritin for allergies and Prilosec for frequent heartburn;

—device approvals included the first drug-eluting stent for angioplasty procedures to open clogged coronary arteries, clearance of the first device for diabetics which integrates a glucose meter and an insulin pump with a dose calculator into one device, and an innovative rapid HIV diagnostic test kit that provides results with 99.6 percent accuracy in as little as 20 minutes.

Lastly, FDA continues to pursue the most cost effective allocation of resources to identify food safety hazards and reduce injury and illness associated with food products. In 2003, building on an HHS strategic goal, FDA implemented new food security regulations that amount to the most substantial expansion of FDA's food safety activities in three decades. The Agency also instituted various new risk communications to improve upon more routine food safety for consumers. Additionally, the Agency continues to practice a cost effective allocation of resources through the targeting of field resources to imports that present the most significant risk. With no sign of import entries decreasing, FDA will intensify these efforts by implementing preventative food safety measures through collaborative arrangements with domestic and foreign governmental bodies.

Patient and Consumer Safety

As beneficiaries of the world's premiere heath care system, Americans should not have to endure preventable medical errors and adverse events related to medical products, dietary supplements, and foods that are responsible for thousands of deaths, millions of hospitalizations, and tens of billions in added health care costs. Americans deserve better than settling for serious health consequences that can't be spotted until many years after a product has been on the market. And Americans and their physicians deserve better than having to rely on limited and often outdated information about risks, benefits, and costs of medical treatments when they are making medical decisions—which, these days, are among the costliest and most important decisions in their lives. So we are taking new steps to make our systems and processes for assuring the safety of food and medical products work better than ever, and to build new ways to assure better patient safety by taking advantage of modern information technology tools. We are thankful for the appropriated increases for patient, medical product safety and our various adverse event systems in the food and medical product centers that we have received in past years.

Preventing medical errors is a top priority at the Department of Health and Human Services and at FDA, and over the past year, FDA has introduced a number of solutions that are enabling a more sophisticated and effective 21st century patient safety system, thus helping lower healthcare costs and ensure longer, healthier lives for Americans. As a result of these new strategic initiatives, more programs are now in place to improve consumer safety than at any time in the Agency's history. In fiscal year 2003, FDA issued a new proposed requirement for bar codes on nearly all prescription drugs and some over-the-counter drugs, as well as machine-readable information on blood and blood components intended for transfusion, that will result in an estimated 413,000 fewer adverse events over the next 20 years. FDA has initiated partnerships that will allow use of external medical databases to investigate specific product safety issues. We continue to encourage the development of "active" reporting systems that use fast, easy web-based reports and systems to get more extensive and timely information on new drugs, important complications, and adverse events that are not well understood. In fiscal year 2003, we also proposed new safety standards to further reduce the incidence of adverse events, such as proposed amendments to radiation-safety standards for diagnostic x-ray equipment and new antibiotic labeling to prevent drug-resistant bacterial strains.

Through enhanced testing and other improvements in blood safety, the risk of transmission of viruses such as HIV, hepatitis B and C has been dramatically reduced. While a blood supply with zero risk of transmitting infectious disease may not be possible, the blood supply is safer than it has ever been. The agency's Center for Biologics Evaluation and Research, worked closely with other FDA Centers, the Center for Disease Control and Prevention, the National Institutes of Health, academic scientists, and the blood and diagnostic industries, in an unprecedented team effort that resulted in the development and implementation of investigational blood donor screening for West Nile Virus within 8 months of when the threat was first recognized. As a result, over 1,000 units of potentially WNV infected blood were identified and removed this past year before they could be transfused.

Lastly, the Agency's Center for Food Safety and Applied Nutrition launched the CFSAN Adverse Event Reporting System covering all food, dietary supplement, and

cosmetic products. Consumers submitted and FDA reviewed more than 6,000 adverse events and consumer complaints in an attempt to ensure consumers are alerted quickly to any potential new dangers. Recently, the CFSAN Adverse Event Reporting System provided information on the dangers of ephedra, which has been banned by FDA.

Better Informed Consumers So many of our stakeholders focus their attention on our mission to protect public health, and ensure the safety of the food supply and the safety and effectiveness of medical products or therapies. However, at the beginning of my testimony I restated FDA's mission which includes mention of our duty to promote public health and "[help] the public get the accurate, science-based information they need to use medicines and foods to improve their health." The public entrusts our subject matter experts and public affairs specialists in Congressional districts across the country at the state and local level to provide consumers with the tools they need to make better-informed choices. These choices range from diet to medical practice recommendations to disease management on the part of the individual. Our role as an educator or informer of the public will become evermore important as patients make more independent decisions about their health and medical care. We must continue to assist the public in how to use their health care dollars as we have done with our generic drug campaigns, and at times protect them from misleading information that could endanger the public's health.

Providing information on diabetes care and prevention is a top priority of FDA and the Administration. In recent years, diabetes rates among people ages 30 to 39 rose by 70 percent. Research shows that good nutrition lowers people's risk for many chronic diseases, including obesity, heart disease, stroke, some types of cancer, diabetes, and osteoporosis. For at least 10 million Americans at risk for type 2 diabetes, proper nutrition along with physical activity can sharply lower their chances of getting the disease.

FDA is also attempting to enhance the consumer understanding of the relationship between diet/obesity and chronic disease. A recently released report by FDA's Obesity Working Group includes recommendations to strengthen food labeling, to educate consumers about maintaining a healthy diet and weight and to encourage restaurants to provide calorie and nutrition information. It also recommends increasing enforcement to ensure food labels accurately portray serving size, revising and reissuing guidance on developing obesity drugs and strengthening coordinated scientific research to reduce obesity and to develop foods that are healthier and low in calories. This effort is important, as a new study from Centers for Disease Control and Prevention (CDC) shows poor diet and inactivity are poised to become the leading preventable cause of death among Americans—causing an estimated 400,000 deaths in 2000. CDC estimates that 64 percent of all Americans are overweight, including more than 30 percent who are considered obese. In addition, about 15 percent of children and adolescents, aged 6 to 19, are overweight—almost double the rate of two decades ago. FDA must promote good nutrition by allowing consumers access to credible, science-based information, and fostering competition based on the real nutritional value of foods rather than on portion size or spurious and unreliable claims. Such labeling can promote better public health by empowering consumers to make smart, healthy choices about the foods that they buy and consume. This is a high priority for the Administration to ensure that health claims are supported by scientific information. President Bush continues to emphasize the improvement of health through better diets and lifestyles.

FDA is undertaking major new efforts to ensure consumers have the most up-to-date, truthful information on the benefits and risks of FDA regulated products. In this arena, FDA fulfills two complementary roles: ensuring that the information sponsors provide about products is accurate and allows for their safe use; and, communicating directly with the public concerning benefits and risks of products FDA regulates.

FDA's strategic plan calls for the Agency to learn how to more effectively communicate the risks and benefits of FDA regulated products to consumers, as well as those in the health and medical professions. The goal is a well-informed public, empowered to make better choices to improve their health. Just this past year, FDA has been involved in a number of consumer education campaigns related to the prudent use of antibiotics, the misuse of pain relievers, the parity between generic and name brand drugs, buying medicines and medical products online, and several other campaigns aimed at addressing a number of areas where the consumer needs to minimize the risks and maximize the benefits of medicine use. FDA also teamed up with women's health organizations to raise awareness about hormone replacement therapy (HRT). The previous year, we conducted a similar campaign to raise awareness about diabetes. We spread the word widely about these efforts and we almost

always try to provide these messages in Spanish to reach as much of the public as possible.

Counterterrorism

FDA is improving its capability to assess and respond effectively to its mission of protecting the security of the Nation's food supply, and ensuring the safety and effectiveness of medical products used to prepare and respond to biological, chemical, or radiological attacks. As Secretary Thompson reported in the July 2003 report entitled, "Ensuring the Safety and Security of the Nation's Food Supply," the Agency is working with other government agencies and the private sector to develop and implement a comprehensive strategy to protect the food supply from attack. These include additional staff for food safety field activities, greater import presence at our Nation's borders, threat assessments, and additional money for food security research. FDA's medical product centers are also working harder and more creatively than ever to speed the availability of the next generation of safer, more effective countermeasures to protect Americans against biological, chemical, nuclear, and radiological agents of terrorism.

In fiscal year 2003, FDA implemented a number of fundamental enhancements on both the food defense and medical countermeasures fronts, in meeting the objectives of this strategic goal. In direct response to this heightened threat, and in conjunction with the Department of Health and Human Service's larger counterterrorism initiatives, FDA has implemented new steps in food defense that represent the most fundamental enhancements in the Agency's food safety activities in many years. FDA's implementation of four new food security regulations prompted by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), will be fundamental and long lasting. Two additional regulations are expected to be finalized in the near future. The Bioterrorism Act gave the Agency some potentially effective tools in identifying, preparing for or responding to terrorist attacks on the food supply. The design and implementation of these four regulations has also spawned a closer working relationship with the U.S. Customs and Border Protection Agency (CBP). Our close relationship led to a recent Memorandum of Understanding (MOU) between FDA and CBP in December 2003 that allows FDA to commission thousands of CBP officers to conduct, on FDA's behalf, investigations and examinations of imported foods in accordance with the prior notice requirements. This cooperative arrangement with FDA's sister enforcement agency was in addition to a more than six-fold increase in the number of field examinations of imported foods from fiscal year 2001 to fiscal year 2003 (78,000) conducted by FDA inspectors and our state partners. Much more needs to be done in this area as we note in our Congressional budget request for an increase of $65 million.

Protecting consumers against terrorism also requires that Americans have access to safe and effective medical countermeasures. This year, FDA has worked closely with scientists and product developers and has taken new steps to speed the development of these safe, effective treatments and preventive vaccines. FDA works closely with NIH, CDC, DHHS, DOD and industry to develop new and improved treatments and vaccines to counter smallpox, anthrax, and other potential emerging biowarfare and public health threats.

FDA has had to become more proactive in identifying possible products for approval for medical countermeasures due to the fact that no known group of patients are currently affected by many of the conditions linked to biological, chemical, or radiological agents. So, in fiscal year 2003, the Agency issued new guidance on the development of Radiogardase ("Prussian Blue") for treatment of internal contamination with thallium or radioactive cesium. Several months later, a firm submitted an application and FDA approved Radiogardase to treat people exposed to radiation contamination from harmful levels of cesium-137 or thallium after identifying existing safety and efficacy data. FDA has worked with other government agencies to facilitate the development of counter-terrorism products, such as vaccines and immune globulins against anthrax, smallpox, and botulism, by resolving regulatory issues and developing assays for potency testing. FDA also took various steps to make sure that manufacturers of medical countermeasures are following Current Good Manufacturing Practices (CGMPs). In 2003, FDA determined that CGMP inspections were lacking for 27 manufacturers of identified medical countermeasures, and the Agency took action to address this. Even without the legislation creating Project BioShield, an act designed in part to provide incentives for developing safer, more effective countermeasures, FDA will remain the only governmental Agency involved with the approval of products necessary to prevent or treat human exposure to these terrorist agents. We hope this Subcommittee supports our $5 million request in fiscal year 2005.

A Strong FDA

The final goal of our Strategic Plan revolves around our world-class, professional workforce that is highly dedicated and committed to making a difference. FDA is aware of the need to maintain the highest level of public trust in its activities. I believe this component of our plan is the bedrock and the most critical component for the success of the Agency. For that reason, the Agency must adequately develop and support its cadre of experienced physicians, toxicologists, chemists, biologists, statisticians, mathematicians, and other highly qualified professions. Since 2001 and into the foreseeable future, we have continually sought new opportunities to improve our management, and efficiencies in our organization, infrastructure and information technology. The practice of efficient risk management certainly applies here as we must strive to adopt management practices that make the Agency's core programs most efficient. The fiscal year 2005 request fully funds the $33.1 million ($20.6 million of which is budget authority) to complete a part of the work force consolidation at White Oak, Maryland.

FDA's adherences to the strategies and goals of the President's Management Agenda have brought about real and positive change toward improving the management of the Agency. These five goals are Strategic Management of Human Capital, Competitive Sourcing, Improved Financial Performance, Expanded E-government, and Budget and Performance Integration. Over the past year, FDA management achieved a number of milestones in the area of "Strategic Management of Human Capital," including the development and phased stand-up implementation of the new shared service organization (SSO). Consolidation into the SSO, combined with improved business processes, will allow FDA to maintain administrative service levels with substantially fewer staff. Another area of continued progress is towards the goal of "improved financial performance." Due to this Subcommittee's continued support, the Agency is making progress towards the eventual replacement of its obsolete legacy accounting systems. The Department-wide Unified Financial Management System will integrate financial management to provide more timely and consistent information, and promote the consolidation of accounting operations that will substantially reduce the cost of accounting services. In addition, FDA has continued its progress towards the consolidation of its IT infrastructure by collaborating with HHS toward achieving its "One HHS" goals and objectives. FDA also competed six agency support functions in fiscal year 2003 to determine the most efficient organization for running and managing each function. The agency determined that the in-house operations for all six functions were the most efficient organizations for providing their respective services. We estimate savings of $16.3 million over a 5 year performance period from just these six organizations. These are just a few examples of FDA's outstanding progress in making efficient use out of limited resources, and practicing efficient risk management.

Fiscal year 2005 Budget Request

As I noted earlier, adequate funding of the Agency's highest priorities is vital to our success. Our fiscal year 2005 President's budget request totals $1.845 billion, including $1.495 billion in budget authority and $350 million in user fees. The Administration proposes both increases and savings related to the President's initiatives for a net budget authority increase of $108.8 million above the fiscal year 2004 Appropriation. Requested increases cover: Cost of Living, Food Defense, Medical Device Review, Medical Countermeasures, Bovine Spongiform Encephalopathy prevention, and the Agency's relocation of the Center for Drugs to the consolidated campus. Additionally, the budget includes management savings achieved through administrative efficiencies and savings achieved by using carryover funds from our Buildings and Facilities account. The user fee increases total more than $40 million. This proposed budget will support a total of nearly 10,800 full time employees.

Cost of Living

Adequate annual pay increases are essential to allow FDA to fully utilize programmatic increases. More than 60 percent of FDA's budget goes toward paying our highly skilled scientific workforce, far more than some Agencies. FDA's labor percentage is higher due to a number of reasons, but most importantly because the Agency's diverse workload requires numerous interdependent specialists in each of the Agency's product areas, the inspectional responsibilities require great geographic diversity to perform duties across the country and around the world, and the number of personnel necessary to monitor the entire life-cycle of all products under the Agency's purview (e.g., clinical drug trials to drug application review to advertising of approved product to actual effect of drug on patient's health). The lack of cost of living increases has the potential to limit or nullify other targeted

increases towards high priority Administration, Congressional and/or mission critical initiatives.

FDA is thankful for this Subcommittee's involvement in providing the Agency with additional funding to cover the cost of inflationary pay increases between fiscal year 2002 and fiscal year 2004. We approach you once again and request that you provide a $14.4 million increase representing a congressionally approved 4.1 percent cost of living increase for calendar year 2004 as well as a 1.5 percent increase for calendar year 2005 as proposed by the President.

Food Defense

As I noted earlier, Food Defense is a major component of FDA's strategic goal to protect America from terrorism as it relates to foods and medical products under our purview. I am also pleased to report that this Subcommittee's support in the hiring of 655 new field staff through the fiscal year 2002 supplemental appropriation as well as the increases provided in fiscal year 2003 is beginning to produce positive results.

Despite some significant progress over the past year with the rapid implementation of the food registration and prior notice regulations and systems, increased training and outreach, record amounts of import examinations, expanded research programs, daily intelligence briefings of FDA officials, etc., additional steps need to be taken to fully prepare our Nation to handle various types of intentional attacks on the food supply.

FDA has spent an extensive amount of time over the past year coordinating this multifaceted plan with the White House Homeland Security Council, the Department of Homeland Security, and the USDA. The result is a joint budget developed with USDA and DHS for food defense to protect the agriculture and food sectors. Based upon the Administration's current knowledge, ability to respond, and capacity to handle an actual attack, FDA requests $65 million in increased funding to shore up five key areas—$35 million for the Food Emergency Response Network [FERN], $15 million for research, $7 million for inspections, $3 million for incident management, and $5 million for biosurveillance. The investments in these particular areas will help develop awareness amongst the various components of the food sector, build upon existing surveillance tools, institute prevention techniques to shield against an attack, prepare for an attack, and provide the capacity to respond if such an event should occur.

It is also vital that the Agency has the capability to coordinate and handle a food defense response with state and local governments and other Federal agencies. We are seeking to build a food defense laboratory network among states, part of a system called FERN. FERN is comprised of labs specializing in food testing for biological, chemical and radiological threat agents and these laboratories will have the capacity to rapidly test a large number of food products. We need to make a distinction here between a corresponding network of labs handled by the Centers for Disease Control and Prevention. CDC is in charge of the Laboratory Response Network that primarily handles clinical testing of human specimens such as blood or urine.

Another system we will build upon with our fiscal year 2005 request is the Electronic Laboratory Exchange Network or eLEXNET. This network is the Nation's first seamless, integrated, secure, web-based data exchange system for food testing information. eLEXNET allows health officials at multiple government agencies engaged in food safety activities to compare, share, and coordinate laboratory analysis findings on food products. Whereas FERN laboratories are involved in the actual analysis of food samples, eLEXNET provides a forum for the exchange of laboratory data. FDA is continuing efforts to expand eLEXNET to provide better nationwide data on food product analyses by regulatory agencies.

Between fiscal year 2001–2005, FDA will increase the number of import food inspections from approximately 12,000 to 97,000. Along with increased inspectional needs, FDA must take the lead in conducting or overseeing research projects that help us understand the effects of contaminated food supplies on people. There are some hostile agents capable of entering our food supply that we don't know how they will react in humans. This is a complex challenge and we must conduct calculated risk assessments and then use limited resources to study human food consumption contaminated with these agents. Our food defense task is challenging and we will make a concerted effort to gain a greater understanding of these threats to the food supply. We currently have over 90 research projects devoted to identifying food adulteration and we hope to improve testing and identification with these projects.

Bovine Spongiform Encephalopathy (BSE)

Although 150 deaths in Europe from variant Creutzfeldt-Jakob disease (vCJD) are linked to consumption of beef from cows with BSE, the economic impact to the farming communities was also devastating. The European Union estimated the cost of BSE contamination in affected countries to reach $107 billion and Canada's recent discovery was costing an average of $11 million a day in lost exports. The Administration is acting vigorously to limit the distribution or spread of any products suspected of carrying BSE following the December 23, 2003 discovery of a Holstein cow with BSE in the state of Washington. On January 26 of this year, FDA announced several new public health measures to strengthen the five existing firewalls that protect Americans from exposure to the agent thought to cause BSE. FDA intends to ban from human food, dietary supplements, and cosmetics a wide range of bovine-derived material so that the same safeguards that USDA implemented for meat products, also apply to food products that FDA regulates. FDA will also prohibit certain feeding and manufacturing practices involving feed for cattle and other ruminant animals. The Agency will strengthen its current controls and implement these new protections by publishing two interim final rules.

In fiscal year 2004, the base budget is $21.5 million for BSE activities across all FDA programs. In fiscal year 2005, we request $8.3 million for a total of $29.8 million in total funding for this initiative. With the increased funding, we will undertake a trilateral approach of increased inspections, enforcement activities, and education. The requested resources will enable the Agency to increase field BSE inspections, sample collections and analyses; increase targeted sample collections and analyses of both domestic and imported animal feed or feed components; fund 2,500 more state inspections of animal feed firms; conduct industry outreach to better inform industry of responsibilities and opportunities to prevent BSE from contaminating animal feed; and strengthen the states' infrastructures to monitor, and respond to, potential feed contamination with prohibited materials. The Administration believes that an $8.3 million request is a relatively modest increase in light of the potential health benefits and cost savings that can be achieved with these resources.

Medical Device

Review FDA is committed to ensuring that the Medical Device User Fee and Modernization Act (MDUFMA) performance goals are met and that the strongest and most effective medical device review program possible is available. The Administration requests a budget authority increase of $25.5 million for a total of $217 million, the amount needed to match the original levels specified by law for fiscal year 2005. On October 29, 2003, OMB Director Josh Bolten wrote to Congress describing the Administration's commitment to support this program at the level intended by MDUFMA in fiscal year 2005 and beyond. Within the approach outlined by Mr. Bolten, the Agency is committed to meeting the original MDUFMA performance goals.

As you know, MDUFMA requires that $205.7 million be appropriated in budget authority each year for FDA's Center for Devices and Radiological Health and related field activities, adjusted for inflation (CPI). The President's fiscal year 2005 budget meets the MDUFMA threshold for fiscal year 2005 appropriations requirements. We look forward to working with Congress to modify MDUFMA to preclude the requirement to appropriate the entire "shortfall" from fiscal year 2003 and fiscal year 2004, in order to continue the user fee program beyond fiscal year 2005. FDA is committed to achieving the performance goals of MDUFMA.

In fiscal year 2005, FDA will utilize the appropriated increases to build upon the success in fiscal year 2003 and fiscal year 2004. In fiscal year 2003, FDA invested user fee and appropriated dollars in a number of ways that will contribute to the ultimate improvement in the review process in later years, including the hiring of more than 50 new scientific, medical, engineering, and other review staff and the development of process improvements to speed review from beginning to end.

Medical Countermeasures

Counterterrorism is a major priority for the FDA and the Department of Health and Human Services. Speeding the development of safe medical countermeasures to improve protection against terrorism and emerging diseases requires that Americans have access to safe and effective medical treatments. Prior to September 11th, FDA had been engaged in coordinated efforts with other Departments to develop and make available better countermeasures for biological, chemical and radiological attacks. The urgency is far greater now and so in fiscal year 2005, FDA will continue to work closely with scientists and product developers and take new steps to speed the development of these safe, effective treatments. FDA requests $5 million

to expedite the review of new drug applications, biologics license applications, generic drugs and over-the-counter medical product countermeasures. The Agency must get involved in each facet of the process from animal studies to dosing requirements to the development of postmarket systems that will be in place to ensure rapid reaction to adverse events. These initiatives are all necessary to ensure that adequate treatments are available for a wide assortment of threats. One of these initiatives is Project BioShield, a program designed to help ensure that medical products are reviewed and approved for safety and effectiveness in the event of war or catastrophic events. The first request for proposals for procurement of a new generation anthrax vaccine through Project BioShield will be initiated shortly.

Center for Drugs Relocation

I can only imagine that it is difficult for members of this Subcommittee to write home about the funding you helped secure for FDA's consolidation of its Washington, D.C. metro area Headquarters Offices from 16 locations to three. However, I think they would be happy to hear that the eventual settling into the three new sites in White Oak, Laurel, and College Park, MD, create greater economies of scale and operational efficiencies. The bottom line is that you will save the American taxpayers money when this project is complete. Although substantial facility needs at White Oak are mostly addressed through the GSA appropriation, FDA must continue to seek your support for relocation costs. In accordance with the President's Management Agenda, the FDA plans to modernize document handling, use shared library and conference facilities, reduce redundancies in a wide range of administrative management tasks, convert to a single computer network, and reduce management layers. Without the requested funds, these management improvements and efficiency gains would be jeopardized.

This current plan calls for the relocation of 1,700 drug review personnel in April of 2005. The budget funds the total need for this move, $33.1 million, and the request includes an increase of $20.6 million in new budget authority. The remainder would come from $2.4 million in the base budget, and $10 million in PDUFA user fees. The General Services Administration has requested $89 million in their fiscal year 2005 budget request to continue construction on the campus. If GSA's subcommittee approves the full request, the building construction would proceed as schedule. However, if GSA does not receive its full request for White Oak, it would have severe financial consequences for FDA. In a 2003 GAO report entitled "Federal Real Property: Executive and Legislative Actions Needed to Address Long-Standing and Complex Problems," the report spells out the Federal Government's problems in managing property, including the inefficient use of space. FDA would be faced with paying unnecessary rental payments for multiple properties unless the funding of construction and relocation costs are synchronized as is currently the plan.

User Fees

In fiscal year 2005, the Agency expects to collect $350 million in user fees, primarily from PDUFA, MDUFMA, and ADUFA fee programs. These user fee programs provide substantial funding that compliment budget authority resources and allow FDA to meet agreed upon performance measures that allow for more rapid reviews of human drugs, medical devices and animal drugs. Additionally, the Agency collects modest fee amounts for the Mammography Quality Standards Act program as well as export certification and color certification programs.

President's Management Agenda & Administrative Consolidation

FDA has been very proactive in streamlining its operations and reducing its administrative expenses. Since November 2001, the Agency has worked with the Department of Health and Human Services to do its part to comply with the President's goal to improve the Strategic Management of Human Capital across the Federal Government. We have demonstrated tremendous success in efforts to delayer our organizational structure, consolidate FDA's decentralized Human Resources (HR) services to a single FDA HR office which has consolidated into the HHS Rockville HR Center; implement a shared services organization that makes best use of administrative resources; plan for consolidated facilities at White Oak Maryland, consolidation of IT activities, and, find efficiencies via competitive sourcing or A–76 studies. Thanks to your support, we also continue to improve financial management at FDA through the planned implementation of a new financial system. In fiscal year 2005, FDA proposes its second straight year of reductions by way of $23.1 million in savings achieved through a seven and a half percent reduction in administrative staff, or a combined reduction of 15 percent between fiscal year 2004 and fiscal year 2005. In addition, no request is being made this year in the Buildings and Facilities appropriation. This represents a savings of $7 million that was de-

voted to higher priority programs. Approximately $4.6 million in carryover funds will sustain the program through fiscal year 2005.

Conclusion

I thank you for your commitment and continued support of FDA. I am confident that the information I provide to you today, and any additional information provided to the Subcommittee following this hearing, will give you further evidence of the Agency's needs in fiscal year 2005, and justify the requested increases these priorities. Thank you for the opportunity to testify today. I look forward to working with all of you and your staffs in the months ahead.

Senator BENNETT. Thank you, sir.

We appreciate all of you.

PROPOSED LEGISLATION

Mr. Bost, there are several requests in the budget for legislative language. One, you have requested a legislative proposal to exclude special pay for military personnel deployed in a designated combat zone if that pay was not received immediately prior to deployment. And second, a request for new legislative language to allow for indefinite funding authority for the Food Stamp Act.

Could you furnish the committee with a written explanation in both of these cases? Senator Kohl and I have determined that we are not going to legislate on an Appropriations Bill without the complete cooperation of the members of the authorizing committee. You have asked us to do this when it is within the purview of the authorizing committee. So I think a clear written statement on those two things would be helpful to us as we make our decision as to whether or not we are going to proceed on that.

Mr. BOST. Certainly Mr. Chairman. I would be more than happy to do so.

[The information follows:]

The President's fiscal year 2005 budget includes a provision to exclude "special" military pay when determining food stamp benefits for deployed members of the armed services. Current rules count all military pay received by the household as earned income in determining household eligibility and benefits. Military personnel receive supplements, such as combat or hazardous duty pay, to their basic pay when they serve in combat, which could reduce a family's benefits or make them ineligible.

The proposal excludes this income as long as it was not received immediately prior to deployment. It supports the families of servicemen and servicewomen fighting overseas by ensuring that they do not lose food stamps as a result of the additional income resulting from their deployment.

This change is being sought in appropriations language for fiscal year 2005 when it is most needed. The cost in fiscal year 2005 is $3 million. Total cost for fiscal year 2005 to 2009 is $12 million if it is needed and enacted in all those years. In fiscal year 2005, we expect to help 2,900 military families.

The indefinite authority proposal in the fiscal year 2005 budget request for the Food Stamp Program would provide such sums as necessary to fund program benefits and payments to States. It would ensure that sufficient resources were always available to provide access to the program for all eligible persons who wish to participate. Unlike the contingency reserve funds, if program costs should significantly exceed budget estimates, it would never be necessary to seek a supplementary appropriation or implement a benefit reduction. This proposal would bring the structure of this critical program in line with other major entitlement programs that already have indefinite authority.

Senator BENNETT. Thank you.

FOOD GUIDE PYRAMID

We have talked to you about the pyramid. I seemed to get a lot of publicity the last time I did that. You say it is currently undertaking a reassessment. Should we just leave it at that and say that it is still being reassessed or do you have any progress reports you want to share with us?

Mr. BOST. We do not really have any progress to report at this point but I think it is real important to know that the first aspect of that is a review of the Dietary Guidelines. Secretary Veneman and Secretary Thompson appointed a group of leading scientists and they are in the midst—I think they have had two meetings and one is upcoming to review the Dietary Guidelines. A review of the Dietary Guidelines will fold into a review of the Pyramid itself.

It is going to come as a result of the challenges we are facing concerning obesity and it continues to come under a great deal of scrutiny.

I think the challenge is trying to be everything to everyone and that is the biggest challenge. Essentially, we eat too much and exercise too little. We are trying to move everybody in this country toward a healthy lifestyle.

Senator BENNETT. Thank you.

LIVE BIRD MARKETS AND AVIAN INFLUENZA

Mr. Hawks, the Washington Post has run some stories on live bird markets and the fact that these markets may be a breeding ground for bird flu or avian influenza. Do you have any information you could provide to us here about that issue? Should we expect the Department to be taking any action with respect to the live bird markets?

Mr. HAWKS. Yes, sir, you sure should. As a matter of fact, there is almost $13 million in our 2005 budget request to address avian influenza. That encompasses the live bird markets.

We are actually, as we speak, moving forward with plans to do more surveillance in those live bird markets, and to do more surveillance in general with respect to low path avian influenza. We are engaged with the States involved and certainly recognize the significance of the live bird markets and the need to address them.

We have already, in the past, actually closed those live bird markets. We have what we call a holiday in those bird markets. We close them for 3 days. We clean, disinfect and depopulate those birds that are there.

It certainly is an area that is of concern to us.

Senator BENNETT. What about those countries that have banned poultry exports from the United States because the bird flu? Are we doing anything to try to get those markets reopened?

Mr. HAWKS. Yes sir, we sure are. We are very much engaged in that.

We have submitted a significant amount of information to our trading partners about what we are doing about the epidemiological investigations that are ongoing.

The one that is the most significant is the high path avian influenza in Gonzalez, Texas. We have completed our surveillance programs there and have found no additional avian influenza.

I will personally be in Mexico City on April 13th, the week after next, to engage in continued discussions with my Mexican counterparts to try to reinforce our desire for them to open the market and follow the appropriate path.

BOVINE SPONGIFORM ENCEPHALOPATHY

Senator BENNETT. While we are on the subject of markets, that brings us now to BSE, and the request on the part of some countries that there be a 100-percent testing of the export market. I understand you are working, as you say, with Mexico, also Japan. Is 100-percent testing of the export market physically possible? Is that a feasible thing?

Mr. HAWKS. Mr. Chairman, we do not think that is the prudent thing to do, to test 100 percent for BSE. As a matter of fact, Mexico has opened parts of its market to us. We continue to move there. But the Japanese market is the one that seems to be the most insistent on an increased level of testing. We have communicated earlier this week with the Japanese our desire to go to the OIE, the Office of International Epizootics, with a panel there to look at our proposals and their proposals to make sure that we are taking the appropriate scientific measures. But we do not believe that 100-percent testing is the appropriate path.

Senator BENNETT. Thank you.

RECALL REPORT BY OFFICE OF INSPECTOR GENERAL

Dr. Murano, I was pleased to hear you talk about the dramatic decline in recall, but the Office of Inspector General has recently released a report—not that recently, but September of 2003—a report critical of several aspects of a specific recall in Colorado. Is that a one-of-a-kind situation that has been dealt with, or do you feel that the OIG has raised some issues that should be examined Department-wide?

Dr. MURANO. Thank you, Mr. Chairman. As you know, that particular recall took place in the summer of 2002, and as that recall was taking place, we identified right away things that we needed to correct to improve our effectiveness at overseeing how recalls are conducted by companies.

We identified a lot of the things that ended up in the OIG report, many months later. We certainly did not wait for the OIG report to start doing something about it, and I think that is what has made a big difference in the results that we see now.

Of course, the OIG takes quite a while to put out their reports. I think the report came out, as you said, last fall. We obviously had been working very, very diligently to address a lot of the issues. We have revised a lot of our directives. We have put in place new policies, and instituted new training modules for our inspectors. I think the proof of it is the recent BSE-related recall that we oversaw, because I think in that particular case, we were able to conduct effectiveness checks in a way that was certainly an improvement over what was done back in 2002.

MEDICAL DEVICE USER FEE AND MODERNIZATION ACT

Senator BENNETT. Thank you.

Dr. Crawford, you and I have visited about MDUFMA—I am learning the acronyms and how to pronounce them—and as you know, I was very supportive of that program, got a commitment from OMB. I am pleased to note—and you mention it in your testimony—how that is being followed through on.

There is speculation that we here on Capitol Hill may have to go to a year-long continuing resolution if we cannot get the appropriations bill through. If they left it to Senator Kohl and me, we would get them all through. But people above our pay grade seem to have some problem.

If there is a year-long continuing resolution, what would be the impact on MDUFMA?

Dr. CRAWFORD. Well, Mr. Chairman, we believe that under the law we would be required and obligated to continue with the user fee program. The problem would be—within the scope of my testimony, I mentioned that we will increase the funding for the medical device program. The President has asked for the increase of funding to $25 million to fully fund this particular program.

Also, within the context of the Administration's budget request, we would seek relief from the shortfalls in fiscal year 2003 and fiscal year 2004. That probably would not be met under a continuing resolution, and so we would have to have another plan in place. If the continuing resolution did not last too long, I think it would be all right in correcting that.

However, we would be working with OMB to try to get an exception under the continuing resolution for this. And I can commit to doing that. Working with them is something we always do, but we would be particularly interested in getting this accomplished.

I was Acting Commissioner before when we got MDUFMA passed, and even though I was here then, I never did learn about the acronym. And I appreciate being educated on it.

I have a real commitment to making this thing work before this administration year is up, and I would feel pretty good about that.

GENERIC BIOLOGICS

Senator BENNETT. A final question. Let's talk about both generic versions of biotech drugs and counterfeit drugs. The Wall Street Journal ran an article a month or so ago: "FDA Takes Step Towards Allowing Generic Versions of Biotech Drugs." Are you familiar with that?

Dr. CRAWFORD. Yes, I am.

Senator BENNETT. Okay. Well, it is clear from reading the article that there is much to be learned, and it seems unusual to me that FDA is developing scientific guidance on how to do something when there is no legal structure by which to do it. There are some serious intellectual property and patient safety questions.

First, wouldn't everybody be better off if there was an open, transparent, and science-driven process before the FDA announces its conclusions?

Dr. CRAWFORD. Yes, I agree. And I also agree that we will need to pay special attention to the regulatory and legal framework that will enable this or not enable it to take place.

When I first testified on this subject some time ago, FDA had been in the mode of saying that generic biologics were not possible

for a number of reasons. Some of them were pharmacological, that is, characterizing what is actually in the biologic so that it can be transferred from one manufacturer to another one, that is, from the pioneer to the generic manufacturer. And the second thing was the very legal and regulatory constraints that you mentioned.

But as the science improves, we have no recourse, Mr. Chairman, but to be open-minded about it and to receive input from the public and from experts in the field, as well as the manufacturers. And although we do not know what the path is at this point to achieve that or even if it is achievable, we are open to suggestions.

We announced just last week a new initiative at FDA called the Critical Path Initiative, in which we are trying to take basic research developments and get them from the laboratory to the bedside quicker. So we intend a large investment, as much as we can afford, in trying to get that kind of thing done. It used to be called technology transfer. It is now much more complex than that and the tools are better.

I do not know what the outcome will be. All I can say to you is that we are open to suggestions from this committee, of course, but from all others.

COUNTERFEIT DRUGS

Senator BENNETT. Thank you. And, very quickly, the FDA earlier this year issued a report on the issue of counterfeit drugs, the efforts of a counterfeit task force. Is that task force report now available?

Dr. CRAWFORD. Yes, it is, and we can make one available to the committee. And if we haven't already done that, I apologize, Mr. Chairman. But it will be done before very much more time passes by, I assure you.

Senator BENNETT. All right. I was going to ask you to list the recommendations and so on, but that can be done with the submission.

Dr. CRAWFORD. We will submit that for the record, separately if we may.

[The information follows:]

COMBATING COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION

EXECUTIVE SUMMARY

The counterfeiting of currency and consumer products are common problems that plague governments and manufacturers around the world, but the counterfeiting of medications is a particularly insidious practice. Drug counterfeiters not only defraud consumers, they also deny ill patients the therapies that can alleviate suffering and save lives. In some countries the counterfeiting of drugs is endemic—with some patients having a better chance of getting a fake medicine than a real one. In many more countries, counterfeit drugs are common. In the United States, a relatively comprehensive system of laws, regulations, and enforcement by Federal and State authorities has kept drug counterfeiting rare, so that Americans can have a high degree of confidence in the drugs they obtain through legal channels. In recent years, however, the FDA has seen growing evidence of efforts by increasingly well-organized counterfeiters backed by increasingly sophisticated technologies and criminal operations to profit from drug counterfeiting at the expense of American patients.

To respond to this emerging threat, Commissioner of Food and Drugs Mark McClellan formed a Counterfeit Drug Task Force in July 2003. That group received extensive comment from security experts, Federal and State law enforcement offi-

cials, technology developers, manufacturers, wholesalers, retailers, consumer groups, and the general public on a very broad range of ideas for deterring counterfeiters. Those comments reinforced the need for FDA and others to take action in multiple areas to create a comprehensive system of modern protections against counterfeit drugs. FDA discussed those ideas, and considered alternatives and criticisms at its public meetings, to develop a comprehensive framework for a pharmaceutical supply chain that will be secure against modern counterfeit threats. The specific approach to assuring that Americans are protected from counterfeit drugs includes the following critical elements:

1. Implementation of new technologies to better protect our drug supply

Because the capabilities of counterfeiters continue to evolve rapidly, there is no single "magic bullet" technology that provides any long-term assurance of drug security. However, a combination of rapidly improving "track and trace" technologies and product authentication technologies should provide a much greater level of security for drug products in the years ahead. Similar anti-counterfeiting technologies are being used in other industries, and FDA intends to facilitate their rapid development and use to keep drugs secure against counterfeits.

a. The adoption and common use of reliable track and trace technology is feasible by 2007, and would help secure the integrity of the drug supply chain by providing an accurate drug "pedigree," which is a secure record documenting the drug was manufactured and distributed under safe and secure conditions.

Modern electronic technology is rapidly approaching the State at which it can reliably and affordably provide much greater assurances that a drug product was manufactured safely and distributed under conditions that did not compromise its potency. FDA has concluded that this approach is a much more reliable direction for assuring the legitimacy of a drug than paper recordkeeping requirements, which are more likely to be incomplete or falsified, and that it is feasible for use by 2007. Radiofrequency Identification (RFID) tagging of products by manufacturers, wholesalers, and retailers appears to be the most promising approach to reliable product tracking and tracing. Significant feasibility studies and technology improvements are underway to confirm that RFID will provide cost-reducing benefits in areas such as inventory control, while also providing the ability to track and trace the movement of every package of drugs from production to dispensing. Most importantly, reliable RFID technology will make the copying of medications either extremely difficult or unprofitable. FDA is working with RFID product developers, sponsors, and participants of RFID feasibility studies to ensure that FDA's regulations facilitate the development and safe and secure use of this technology. FDA is also working with other governmental agencies to coordinate activities in this area.

b. Authentication technologies for pharmaceuticals have been sufficiently perfected that they can now serve as a critical component of any strategy to protect products against counterfeiting.

Authentication technologies include measures such as color shifting inks, holograms, fingerprints, taggants, or chemical markers embedded in a drug or its label. The use of one or more of these measures on drugs, starting with those considered most likely to be counterfeited, is an important part of an effective anti-counterfeiting strategy. Because counterfeiters will adapt rapidly to any particular measure and because the most effective measures differ by product, the most effective use of authentication technology will vary by drug product over time. FDA intends to clarify its policies and procedures to help manufacturers employ and update these technologies safely and effectively. In particular, FDA plans to publish a draft guidance on notification procedures for making changes to products (e.g., addition of taggants), their packaging, or their labeling, for the purpose of encouraging timely adoption and adaptation of effective technologies for detecting counterfeit drugs. FDA also intends to continue to evaluate and provide information to stakeholders on forensic technologies (e.g., use of product fingerprinting, addition of markers) and other analytical methods that allow for rapid authentication of drug products. FDA also plans to support the development of criteria that contribute to counterfeiting risk, and/or the development of a national list of drugs most likely to be counterfeited based on these criteria, to assist stakeholders in focusing their use of anti-counterfeiting technologies as effectively as possible.

2. Adoption of electronic track and trace technology to accomplish and surpass the goals of the Prescription Drug Marketing Act

At the time PDMA was enacted the only way to pass on a pedigree for drugs was to use paper, which has posed practical and administrative challenges. RFID technology, which would provide a de facto electronic pedigree, could surpass the intent of PDMA and do so at a lower cost. In light of the rapid progress toward much more

effective electronic pedigrees that can be implemented within several years, FDA intends to continue to stay its regulations regarding certain existing pedigree requirements to allow suppliers to focus on implementing modern effective pedigrees as quickly as possible.

3. Adoption and enforcement of strong, proven anti-counterfeiting laws and regulations by the States

Because States license and regulate wholesale drug distributors they have an important role in regulating the drug distribution supply chain. The FDA is working with the National Association of Boards of Pharmacy on its effort to develop and implement revised state model rules for licensure of wholesale drug distributors. Such rules will make it difficult for illegitimate wholesalers to become licensed and transact business, thus making it easier to deter and detect channels for counterfeit drugs. Some states have already reduced counterfeit threats by adopting such measures. FDA will continue working with NABP and states to facilitate adoption of the Model Rules.

4. Increased criminal penalties to deter counterfeiting and more adequately punish those convicted

Although increased criminal penalties would not affect FDA's regulatory framework for overseeing the U.S. drug supply, they would provide an added deterrent to criminals who work to counterfeit our citizens' medications. FDA has requested that the United States Sentencing Commission amend the sentencing guidelines to increase substantially the criminal penalties for manufacturing and distributing counterfeit drugs and to provide for enhanced penalties based on the level of risk to the public health involved in the offense.

5. Adoption of secure business practices by all participants in the drug supply chain

Effective protection against counterfeit drugs includes actions by drug producers, distributors, and dispensers to secure their business practices such as ensuring the legitimacy of business partners and refusing to do business with persons of unknown or dubious background, taking steps to ensure physical security, and identifying an individual or team in the organization with primary responsibility for ensuring that effective security practices are implemented. The wholesalers have already drafted a set of secure business practices and FDA will continue to work with other major participants of the drug supply chain to develop, implement, and disseminate such business practices, through such steps as issuing guidance and supporting the development of industry best practices. To help ensure secure business practices, FDA intends to increase its inspection efforts of re-packagers whose operating procedures place them at increased risk for the introduction of counterfeit drugs.

6. Development of a system that helps ensure effective reporting of counterfeit drugs to the agency and that strengthens FDA's rapid response to such reports

If counterfeit drugs do enter the American marketplace, procedures should be in place to recognize the hazard and alert the public quickly and effectively. FDA plans to take new steps to encourage health professionals to report suspected counterfeit drugs to FDA's MedWatch system. FDA also intends to create a Counterfeit Alert Network to provide timely and effective notification to affected health professionals and the public whenever a counterfeit drug is identified.

7. Education of consumers and health professionals about the risks of counterfeit drugs and how to protect against these risks

FDA will develop educational materials, including new tools on the FDA website at *www.fda.gov*, new public service announcements, and new educational partnerships with consumer and health professional organizations, to help consumers avoid counterfeits. FDA will enhance its educational programs for pharmacists and other health professionals about their role in minimizing exposure to, identifying, and reporting counterfeits.

8. Collaboration with foreign stakeholders to develop strategies to deter and detect counterfeit drugs globally

Counterfeit drugs are a global challenge to all nations, and criminal counterfeiting operations are increasingly operating across national borders. FDA intends to work with the World Health Organization, Interpol, and other international public health and law enforcement organizations to develop and implement worldwide strategies to combat counterfeit drugs.

The steps described in this report are intended to secure the safety and of the U.S. drug supply, which the FDA regulates. The FDA does not have the legal au-

thority or resources to assure the safety and efficacy of drugs purchased from other countries outside our domestic drug distribution system, or from unregulated Internet sites that are not run by pharmacies licensed and regulated by U.S. States.

A. Purpose of the Anti-Counterfeiting Initiative

The actions described in this report are based on the work of an internal FDA Counterfeit Drug Task Force [1], which was formed in July 2003 by Commissioner of Food and Drugs Mark McClellan, M.D., Ph.D., with the goals of:

—Preventing the introduction of counterfeit drugs and biologics into the U.S. drug distribution chain;
—Facilitating the identification of counterfeit drugs and biologics;
—Minimizing the risk and exposure of consumers to counterfeit drugs and biologics; and
—Avoiding the addition of unnecessary costs to the prescription drug distribution system, or unnecessary restrictions on lower-cost sources of drugs.

B. Scope of the Problem

FDA believes that counterfeiting is not widespread within the system of manufacturing and distributing pharmaceuticals legally in the United States, as a result of an extensive system of Federal and State regulatory oversight and steps to prevent counterfeiting undertaken by drug manufacturers, distributors, and pharmacies. However, the agency has recently seen an increase in counterfeiting activities as well as increased sophistication in the methods used to introduce finished dosage form counterfeits into the otherwise legitimate U.S. drug distribution system. FDA counterfeit drug investigations have increased to over 20 per year since 2000, after averaging only 5 per year through the late 1990's. (See Figure 1—Chart of FDA investigations) Increasingly, these investigations have involved well-organized criminal operations that seek to introduce finished drug products that may closely resemble legitimate drugs yet may contain only inactive ingredients, incorrect ingredients, improper dosages, sub-potent or super-potent ingredients, or be contaminated. Thus, drug counterfeiting poses real public health and safety concerns today, and may pose an even greater threat in the future if we fail to take preventative measures now. As counterfeiters continue to seek out new technologies to make deceptive products and introduce them into legitimate commerce, our systems for protecting patients must respond effectively.

[1] The Task Force consists of senior agency staff from the Office of the Commissioner (Office of Policy and Planning, Office of External Affairs, and Office of the Chief Counsel), Office of Regulatory Affairs, the Center for Drug Evaluation and Research, and the Center for Biologics Evaluation and Research.

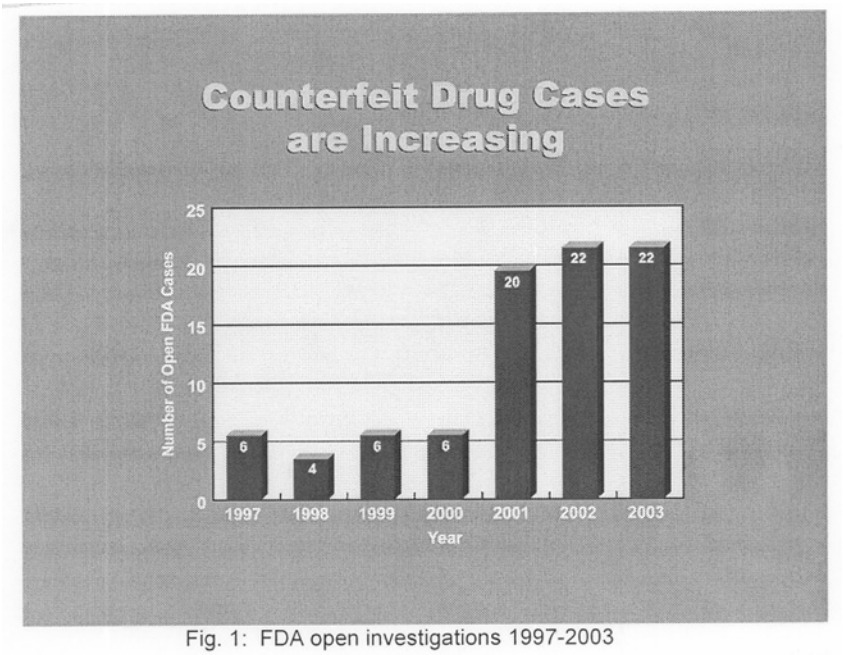


Fig. 1: FDA open investigations 1997-2003

Although exact prevalence rates in the United States are not known, outside the U.S. drug counterfeiting is known to be widespread and affect both developing and developed countries. In some countries more than half of the drug supply may consist of counterfeit drugs. For example, recent reports have detailed that more than 50 percent of anti-malarials in Africa are believed to be counterfeit. In virtually all countries, counterfeit drug operations have been uncovered in recent years.

C. What is in this Report

The body of this report contains a range of findings that have broad support from industry stakeholders and the public to identify and address the vulnerabilities in the U.S. drug distribution system to counterfeit drugs.

This report is based on the potential options discussed in the Task Force's Interim Report, the comments FDA received in response to that report, our internal discussions, and on information gathered and reviewed by the Task Force including:

—Meetings with government agencies, manufacturers, wholesalers, retailers, professional and trade associations, standard-setting organizations, consumer groups, and manufacturers of anti-counterfeiting measures;
—Reviewing reports prepared by, or on behalf of, Federal and State governments;
—Sponsoring a public meeting where 72 presentations were made
—Sponsoring a technology forum which included 54 exhibits
—Reviewing public comments to the anti-counterfeiting initiative docket
—Site visits to manufacturing facilities, wholesale distribution centers, retailers, radio-frequency identification (RFID) laboratories and pilot facilities;
—Attendance at stakeholder task force meetings and industry RFID feasibility study meetings
—Meetings with academic and industry experts

Appendix A contains the Counterfeit Alert Network Co-sponsorship agreement. See *www.fda.gov/oc/initiatives/counterfeit/* for background information that was included in the Task Force's Interim Report (released on October 2, 2003) as well as a detailed discussion of the comments FDA received. Appendix B contains a more detailed discussion of the comments FDA received and considered in developing the final report.

The FDA is grateful for the input and universal support, not only with regard to the creation of the task force, but also with regard to the need for securing the Nation's drug supply.

D. Securing our Nation's Drug Supply

To secure the U.S. drug supply chain, there are several areas that deserve attention, including the areas of technology, business practices, legislation, regulation, public awareness and education, creation of an alert network, and international cooperation.

1. TECHNOLOGY

a. Unit of Use Packaging

(1) What FDA sought comment on:

Whether to package all finished dosage form drugs in unit of use packaging as appropriate for the particular product (e.g., tablet, multi-dose vial) at the point of manufacture?

(2) What the comments said:

Comments cited a large number of benefits, including eliminating the need for repackaging and improved patient compliance, as well as a large number of costs, including those associated with shifting production from bulk packaging. The cost hurdle to counterfeiters, created by unit of use packaging, was said not to be high enough for it to be effective as a stand-alone anti-counterfeiting measure. A detailed discussion of the comments is in Appendix B.

(3) Discussion:

Although single unit containers (e.g., blister packs) usually come to mind, unit of use packaging is any container closure system designed to hold a specific quantity of drug product for a specific use and dispensed to a patient without any modification except for the addition of appropriate labeling.

Unit of use packaging does not create a sufficiently high level of security to justify its use as a stand-alone anti-counterfeiting measure. However, because of its many other benefits, which may vary on a product specific basis (e.g., tablets, liquid forms), manufacturer initiated cost-benefit analyses of particular products, starting with newly approved products and products that are likely to be counterfeited, are likely to show that unit of use packaging could be effective as one layer in a multi-layered anti-counterfeiting strategy.

(4) FDA Conclusions:

Unit of use packaging can be beneficial in fighting counterfeit drugs.

—It would be beneficial for all manufacturers and re-packagers to analyze the costs and benefits of using unit of use packaging for each product, starting with newly approved products and products that are likely to be counterfeited, and to consider implementing unit of use packaging for products where the benefits are equal to or outweigh the costs;

—Unit of use packaging can be helpful, but only as one layer in a multi-layered anti-counterfeiting strategy;

—FDA intends to encourage adoption of unit of use packaging by: inviting stakeholders and other interested individuals and organizations to submit research on the relative costs and benefits of unit of use packaging to assist FDA in developing future policy; and encouraging standard setting bodies to develop standards for unit of use packaging with the goal of reducing its costs (e.g., in areas such as size, shape, and pill organization).

b. Tamper Evident Packaging

(1) What FDA sought comment on:

Whether to use tamper evident packaging from the point of manufacture, for all dosage forms, active pharmaceutical ingredients (APIs), and bulk chemicals?

(2) What the comments said:

The comments on tamper evident packaging mirrored the comments on unit of use packaging.

(3) Discussion:

Decisions to employ tamper evident packaging on prescription drug containers as an anti-counterfeiting measure require a product specific cost-benefit analysis. As with unit of use packaging, FDA does not believe that tamper evident packaging presents a high enough hurdle for counterfeiters to make it effective as a stand-alone anti-counterfeiting measure.

(4) FDA Conclusions:

Tamper evident packaging may be beneficial in fighting counterfeiting of prescription drugs.

—It would be beneficial for manufacturers and re-packagers to consider using tamper evident packaging for prescription product containers, starting with products likely to be counterfeited or newly approved products, where the benefits are equal to or outweigh the costs;

—Tamper evident packing can be helpful, but only as one layer in a multi-layered anti-counterfeiting strategy.

c. Authentication Technology

(1) What FDA sought comment on:

Whether to incorporate at least two types of anti-counterfeiting technologies into the packaging and labeling of all drugs, at the point of manufacture, with at least one of those technologies being covert (i.e., not made public, and requiring special equipment or knowledge for detection) starting with those products at high risk of being counterfeited and where the introduction of counterfeit product poses a serious health risk;

Whether to incorporate a taggant, chemical marker, or other unique characteristics into the manufacturing process of all drugs that is only identifiable with the use of sophisticated analytic techniques starting with those products at high risk of being counterfeited and where the introduction of counterfeit product poses a serious health risk; and

Whether to issue FDA guidances concerning the appropriate use of anti-counterfeiting technologies and the application and review process for labeling and packaging changes or product changes such as incorporation of taggants, chemical markers, or other unique characteristics into the product for the purpose of product authentication.

(2) What the comments said:

The comments stressed that there was no "silver bullet" anti-counterfeiting technology because sophisticated, well-financed counterfeiters can defeat any anti-counterfeiting measure. Therefore, the best strategy is to use multiple, periodically changing, authentication measures on a product specific basis after doing a risk analysis that takes into account the risk that the product will be counterfeited and the public health risk if the product is counterfeited.

Given the rapid developments in anti-counterfeiting technology and the dangers of aiding counterfeiters by locking in or requiring certain technologies, most comments stressed that the FDA should not mandate the use of specific anti-counterfeiting technologies.

FDA issuance of guidance concerning the agency's application and notification policies and procedures related to incorporating anti-counterfeiting measures into products (e.g., taggants), or labeling and packaging (e.g., inks, holograms) was universally supported.

A detailed discussion of the comments is in Appendix B.

(3) Discussion:

FDA agrees that the danger of unwittingly assisting counterfeiters and stifling technologic development outweigh the benefits that would accrue if it were to mandate the use of a specific authentication technology at this time. Furthermore, the decision to deploy authentication technologies is best made by the manufacturer, based on a product specific risk-benefit analysis that, in the future, should take into account whether mass serialization and radio-frequency identification technology (see below) is being used for tracking and tracing the drug.

However, due to the high costs and technical barriers that authentication technologies create for counterfeiters, their use is a critical component of any effective multi-layered anti-counterfeiting strategy, especially for products that are likely to be counterfeited. Therefore, FDA believes that an appropriate role for it is to facilitate the use of authentication technologies by reducing any regulatory hurdles that may exist relating to their use.

(4) FDA Conclusions:

Existing authentication technologies have been sufficiently perfected they can now serve as a critical component of any strategy to protect products against counterfeiting.

—The use by manufacturers and re-packagers of one or more authentication technologies on their products, particularly those likely to be counterfeited, would protect the public health and diminish counterfeiting;

—To facilitate the use of authentication technologies on existing products, FDA plans to publish a draft guidance on notification procedures for making changes to products (e.g., addition of taggants) their packaging, or their labeling for the purpose of deterring and detecting counterfeit drugs;
—FDA plans to continue to evaluate and disseminate information to stakeholders on developing forensic technologies (e.g., use of product fingerprinting, addition of markers) and other analytical methods that allow for rapid authentication of drug products.

d. Identification of Products likely to be counterfeited

(1) What FDA sought comment on:

Are all products at high risk for being counterfeited?
How can products at high risk for being counterfeited be identified?
What criteria should be used to determine if a product is at high risk for being counterfeited?

(2) What the comments said:

Although a few comments suggested that all products were at high risk for being counterfeited, most of the comments FDA received supported the idea of developing criteria by which stakeholders could determine which products are likely to be counterfeited and/or developing a national list of products likely to be counterfeited based on these criteria. There was general agreement that the existence of state specific lists, each with its own regulatory requirements, could inhibit commerce and adversely affect the availability of drugs. FDA notes that the State of Florida has already published a list of "specified products" (i.e., a list of drugs most likely to be counterfeited) that is being used to implement state pedigree requirements. A detailed discussion of the comments is in Appendix B.

(3) Discussion:

Due to the large number of drugs with the potential to be counterfeited, FDA does not believe it is possible to create a comprehensive list of all such drugs. However, FDA does believe that a national list of those drugs most likely to be counterfeited and/or a set of criteria to use for determining those drugs would be useful for stakeholders to use at their discretion. Uses could include:
—Assisting manufacturers and re-packagers in making decisions whether to use authentication technologies and unit of use packaging;
—Assisting wholesalers in developing purchasing policies and allocating resources for detecting counterfeits;
—Assisting retailers in targeting certain drugs for authentication and patient education prior to dispensing;
—Assisting states in implementing regulatory requirements;
—Assisting stakeholders in developing migratory paths to adoption of mass serialization and electronic track and trace technology.

FDA strongly supports the development of such a set of criteria, or a list based on these criteria, that has the support and participation of all stakeholders. Regular input from interested parties as well as the ability to add or delete drugs from the list on short notice are important parts of the process.

FDA believes that members of regulated industry are better positioned at this time than FDA to develop a process for creating, maintaining, and updating such a list (and/or set of criteria).

(4) FDA Conclusions:

FDA has concluded that there would be great value in the creation of a national list of drugs most likely to be counterfeited based on factors that are likely to contribute to counterfeiting risk.
—FDA intends to encourage stakeholders and standards setting organizations to work together to create a national list of drugs most likely to be counterfeited, based on an assessment of criteria for determining counterfeit risk;
—The best result would be achieved if all stakeholders, including FDA, and other interested parties participate in developing a list, or criteria for determining, drugs most likely to be counterfeited;
—Any such list, and/or criteria, would be most effective if made publicly available to all stakeholders.

FDA is aware of only one national list of drugs most likely to be counterfeited. The list was developed by the National Association of Boards of Pharmacy and is available at *www.nabp.org*.

e. Radio-frequency Identification (RFID) Technology

(1) What FDA sought comment on:

Whether a pedigree for all drug products can be achieved by phasing in track and trace technology (i.e., electronic pedigree) starting at a case and pallet level for products likely to be counterfeited and progressively including all products at the case, pallet, and package level; and

Whether, as an interim measure, prior to widespread adoption of track and trace technology all drugs and biologics likely to be counterfeited should be tracked and traced either by limiting the number of transactions of the product or by using available track and trace technology, identifying the drug at the case and pallet level, and preferably at the product level, throughout the distribution system.

(2) What the comments said:

There was universal support for the adoption of electronic track and trace technology. RFID was cited as being the technology with the strongest potential for securing the supply chain but that it was not ready for widespread commercial use with pharmaceutical products. Many costs, potential benefits, and unresolved issues related to RFID were cited. The potential benefits included the ability to control inventory and conduct rapid, efficient recalls, while costs that could hinder the adoption of RFID included purchase of tags and other hardware, integration into existing information systems, and compliance with regulatory requirements (e.g., labeling, electronic records). Important unresolved issues included the need to develop standards and business rules for RFID, the need to address database management issues, and the need to determine the effect of RFID on product quality.

FDA was also informed that some companies are planning feasibility studies concerning business uses of RFID for early this year and that other activities related to creating standards, business rules, and migratory pathways for RFID are also ongoing. A detailed discussion of these activities and other comments concerning RFID is in Appendix B.

(3) Discussion

Use of mass serialization to uniquely identify all drug products intended for use in the United States is the single most powerful tool available to secure the U.S. drug supply. Mass serialization involves assigning a unique number (the electronic product code or EPC) to each pallet, case, and package of drugs and then using that number to record information about all transactions involving the product, thus providing an electronic pedigree from the point of manufacture to the point of dispensing. This unique number would allow each drug purchaser to immediately determine a drug's authenticity, where it was intended for sale, and whether it was previously dispensed.

Although there is general agreement that widespread use of mass serialization is inevitable, several important issues remain unresolved, including the migratory paths that participants in the drug distribution system will follow as they begin to serialize their products, and the most likely timeline for widespread commercial use.

It currently appears that the technology most likely to bring mass serialization into widespread commercial use by the pharmaceutical industry is RFID, although two-dimensional bar codes may be used for some products. RFID technology includes not only the silicon tags containing the EPC, but also antennas, tag readers, and information systems that allow all users to identify each package of drugs and its associated data. This data can be used not only to authenticate drugs but also to manage inventory, conduct rapid, targeted recalls, prevent diversion, and ensure correct dispensing of prescriptions.

Acquiring and integrating RFID technology into current manufacturing, distribution, and retailing processes will require considerable planning, experience, and investment of resources. Currently, some manufacturers, wholesalers, and retailers are developing business plans and testing mass serialization using RFID while others are taking a wait and see approach. Due to rapid technologic advancements, the lack of significant market place experience with it in the pharmaceutical supply chain, each participant is best situated to determine his optimal paths to adopting it.

Therefore, FDA has identified near term actions, described below, for it to take in order to facilitate the performance of mass serialization feasibility studies using RFID, and to assist stakeholders as they migrate towards the use of RFID technology.

In the long term, after there is significant market place experience with RFID, FDA plans to propose or clarify, as necessary and appropriate, policies and regulatory requirements relating to the use of RFID. Labeling, electronic records, product quality, and Current Good Manufacturing Practices (cGMP) requirements are

issues that have arisen in connection with RFID. However, regulatory or policy determinations regarding these, or other, issues should not be made until they can be informed by sufficient data and significant marketplace experience with RFID. FDA has also identified a series of actions, discussed below, that would help industry stakeholders and standard-setting organizations achieve this goal.

Lastly, stakeholders will need to ensure that they comply with the patient privacy protections provided by the Health Insurance Portability and Accountability Act as they implement use of RFID technology.

(4) FDA Conclusions:

The adoption and common use of RFID as the standard track and trace technology, which is feasible in 2007, would provide better protection.

—Due to industry's current initiatives, mass serialization and RFID technology is likely to be adopted according to the following timeline:

January—December 2004

—Performance of mass serialization feasibility studies using RFID on pallets, cases, and packages of pharmaceuticals;

January—December 2005

—Mass serialization of some pallets and cases of pharmaceuticals likely to be counterfeited;

—Mass serialization of some packages of pharmaceuticals likely to be counterfeited; and

—Acquisition and use of RFID technology (i.e., ability to read and use the information contained in RFID tags and the associated database) by some manufacturers, large wholesalers, some large chain drug stores, and some hospitals.

January—December 2006

—Mass serialization of most pallets and cases of pharmaceuticals likely to be counterfeited and some pallets and cases of other pharmaceuticals;

—Mass serialization of most packages of pharmaceuticals likely to be counterfeited; and

—Acquisition and use of RFID technology (i.e., ability to read and use the information contained in RFID tags and the associated database) by most manufacturers, most wholesalers, most chain drug stores, most hospitals, and some small retailers.

January—December 2007

—Mass serialization of all pallets and cases of pharmaceuticals;

—Mass serialization of most packages of pharmaceuticals; and

—Acquisition and use of RFID technology (i.e., ability to read and use the information contained in RFID tags and the associated database) by all manufacturers, all wholesalers, all chain drug stores, all hospitals, and most small retailers.

—FDA plans to assist, to the extent necessary and appropriate, in facilitating the rapid, widespread adoption of RFID in the drug distribution system by working with stakeholders in the following areas:

  —Addressing any regulatory and policy issues related to the performance of feasibility studies;

  —Addressing any regulatory and policy issues relating to the notification requirements associated with implementation of RFID;

  —Addressing any product quality concerns and data issues related to the performance of feasibility studies;

  —Reviewing protocols for feasibility studies;

  —Working with other governmental agencies to coordinate activities;

  —Encouraging stakeholders to convene meetings of supply chain participants to identify, discuss, and propose solutions to technical, business, and policy issues related to the use of RFID technology in the pharmaceutical distribution system; and

  —Exploring the need for any other processes and venues that might be needed to assist stakeholders as they migrate towards the use of RFID technology.

—FDA intends to regularly review the pace at which RFID is being adopted in the U.S. drug distribution system;

—FDA plans to publish or clarify, as appropriate, regulatory requirements, policy guidance, and product quality testing requirements related to the use of RFID after sufficient data and marketplace experience with RFID are available to adequately inform our decision-making; and

—FDA intends to consider taking further steps to facilitate the adoption of mass serialization.

1. Business steps for industry

Each industry stakeholder interested in implementing RFID would benefit from the following steps:

—Create an internal team focused on the adoption of mass serialization and use of RFID technology;
—Perform internal feasibility studies to gain experience with mass serialization and RFID technology and to identify internal business issues requiring resolution;
—Perform external pilot studies with stakeholders across the supply chain to gain experience using mass serialization and RFID and to identify opportunities, barriers and external business issues associated with them;
—Develop policy and a business case for the use of mass serialization and RFID;
—Cooperate and work with other stakeholders and government agencies to develop infrastructure and information systems to use with mass serialization of pallets, cases, and packages of drugs;
—Participate on standard setting groups developing technical standards and business rules for use of mass serialization and RFID;
—Work with government agencies and other members of the supply chain to identify and address regulatory and economic issues that could delay the adoption of mass serialization and RFID; and
—Educate other members of the supply chain and government agencies about mass serialization and RFID.

To the extent possible, it would be most useful for interested firms to perform these actions concurrently. For example, standards development requires knowledge gained from feasibility studies in order to move forward, and vice versa.

2. Standards Setting Issues

Any effort to develop standards for mass serialization of pallets, cases, and packages would be most effective if it addressed the following issues:

—Minimum Information Requirements for the serial number—in the case of RFID tags this means containing a mass serialization code that uniquely identifies the object to which it is attached (e.g., minimum of 96 bits of information);
—Communication protocol standards—in the case of RFID this means standard protocols for interrogating and reading tags;
—Reader Requirements—Readers of mass serialization codes should be interoperable (e.g., readers must use protocols that allow them to read multiple classes of tags or bar codes, as applicable) and should be able to automatically upgrade software over an information network;
—Pedigree requirements—this means that databases containing transaction information should be compatible (e.g., format, mark-up language);
—Information Network Requirements
  —1. Database Structure (e.g., centralized vs. distributive)
  —2. Data ownership
  —3. Data access (to meet business, track and trace, and recall needs)
  —4. Data Access controls to assure information security;
—Software Requirements—all applications should be compatible and compliant to assure global interoperability; and
—Best use of Frequencies—(e.g., 13.56 megahertz on packages and 915 megahertz on cases and pallets due to interference and read range issues).

2. REGULATORY INITIATIVES AND STATE MODEL RULES

All levels of government, in addition to the private sector, should take responsibility for ensuring the safety and security of the U.S. drug distribution system. Each level has a role in deterring and preventing the introduction of counterfeit drugs into the Nation's drug supply chain. To complement and build on the technology measures described above, regulatory and legislative steps at all levels of government may be necessary. At the Federal level, FDA is taking steps to meet the objectives of the Prescription Drug Marketing Act (PDMA), which is intended to address vulnerabilities in the U.S. drug distribution system. At the State level, it would be beneficial for states to strengthen their provisions governing wholesale distribution, as described below in the revised Model Rules for Licensure of Wholesale Distributors. And, FDA plans to pursue increased criminal penalties for counterfeiting in the United States Sentencing Commission's sentencing guidelines.

A. Prescription Drug Marketing Act (PDMA)

(1) What FDA sought comment on:

What are the most effective ways to achieve the goals of PDMA and, given recent or impending advances in technology discuss the feasibility of using an electronic pedigree in lieu of a paper pedigree?

(2) What the Comments Said:

Many of the comments that discussed PDMA acknowledged the limitations and concerns of full implementation of PDMA. However, many comments also supported the use of paper pedigrees for their deterrent value and as a means to verify prior sales through due diligence. A risk-based approach to implementing PDMA, which focuses on those drugs that are at high risk of being counterfeited, was suggested, as well as maintaining a full pedigree that documents all sales and transactions back to the manufacturer for drugs and high risk. One comment suggested an interim solution of "one forward, one back" pedigree for high-risk drugs. However, a number of the comments noted the high cost and incomplete protection provided by such paper requirements, especially as a general interim measure; by the time these costly requirements were phased in, they could be replaced by a more modern system. A majority of the comments supported the eventual use of an electronic pedigree for all drug products in the supply chain and indicated that an electronic pedigree should be considered as a modern solution to fulfilling and exceeding the PDMA goals, and urged FDA to take steps to help achieve a reliable pedigree solution as quickly as possible. As noted above, FDA believes that substantial progress toward a more cost-effective solution than incomplete and costly paper pedigrees is possible within the next several years. A detailed discussion of the comments is in Appendix B.

(3) Discussion:

FDA has worked closely with affected parties to identify and resolve concerns related to the implementation of the pedigree requirements of the PDMA. Through the various public comment opportunities over the years, the agency has heard mixed reviews about the value, utility, and difficulty of implementing a paper pedigree that identifies each prior sale, purchase, or trade of such drug. The comments received in response to questions raised in the Interim Report confirm that these concerns continue.

FDA is encouraged by the enthusiasm and interest that stakeholders in the U.S. drug supply chain have expressed toward the adoption of sophisticated track and trace technologies that are more reliable than paper pedigrees. As discussed above, there appears to be movement by industry toward implementation of electronic track and trace capability in 2007. When this is in place, RFID should be able to function as a de facto electronic pedigree that follows the product from the place of manufacturer through the U.S. drug supply chain to the final dispenser. If developed properly, this electronic pedigree could be used to meet the statutory requirement in 21 U.S.C. § 353(e)(1)(A) to provide a pedigree under certain circumstances.

In the interim, until the electronic pedigree is in widespread use, voluntary adoption of multi-layer strategies and measures discussed in this report would reduce the likelihood that counterfeit drugs will be introduced into the U.S. drug distribution system. These measures, combined with RFID technology, can help provide effective long-term protections that will minimize the number of counterfeit drug products in the United States distribution system.

As discussed in a notice published in the Federal Register in conjunction with the publication of this report, FDA plans to continue to stay the implementation of 21 CFR §§ 203.3(u) and 203.50. However, the agency intends to continue to reassess the stay of implementation on an annual basis. The agency will monitor closely whether progress toward the implementation of electronic pedigrees continues at the rapid pace evident in this task force analysis. Our plan to reassess the stay annually is part of the agency's strong commitment to see that effective product tracing is implemented as quickly as possible. The agency also encourages wholesalers to provide pedigree information that documents the prior history of a drug product, particularly for drugs most likely to be counterfeited, even when the passing of such a pedigree is not required by the Act. The suggestion from the comments that there be a one-forward, one-back pedigree for high-risk drugs in the interim, until an electronic pedigree is uniformly adopted, may have merit. However, FDA believes that Congress would have to amend section 503(e) of the Act if such a system is to become a requirement.

(4) FDA Conclusion:

Adoption of electronic track and trace technology would help stakeholders meet and surpass the goals of PDMA. Therefore, FDA intends to focus its efforts on facilitating industry adoption of this technology within the next few years.

—To allow stakeholders to continue to move toward the goal of an electronic pedigree, FDA intends to delay the effective date of 21 CFR §§ 203.3(u) (definition of ADR criterion) and 203.50 (specific requirements regarding pedigree) until December 2006;

—By December 2006, FDA intends to determine whether to further stay the regulations or take other appropriate regulatory action.

B. Model Rules for Wholesale Distributor Licensing Strengthened

(1) What FDA sought comment on:

How should the NABP Model Rules for Licensure of Wholesale Distributors (Model Rules) be updated?

Whether FDA regulations at 21 CFR Part 205, should be updated, as appropriate, to make it consistent with updates to the NABP Model Rules?

(2) What the Comments Said:

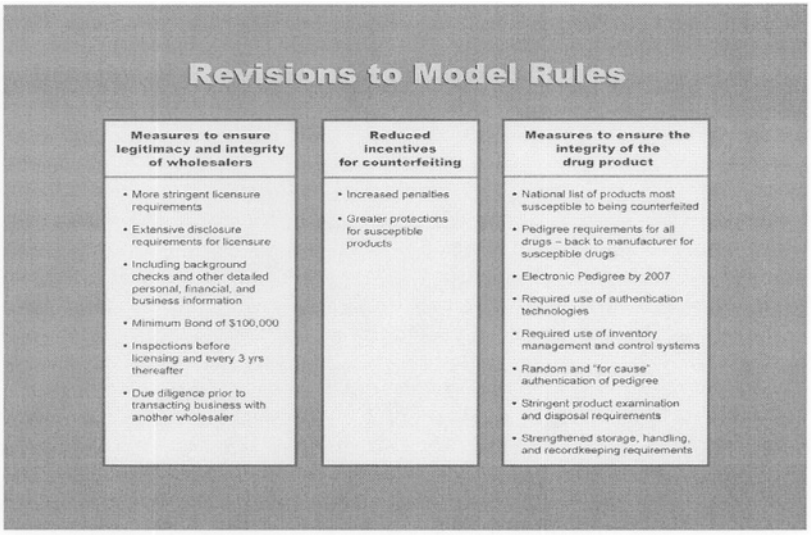
The comments overwhelmingly supported strengthening state requirements governing the licensure and oversight of wholesale distributors. Many comments cited the systemic weaknesses in the oversight of the wholesale drug industry and that existing inspection and due diligence processes are often insufficient to detect criminal activity. Some comments noted the positive steps already taken by some states, such as Florida, toward more effective regulation of wholesale distributors. For example, Florida has implemented more stringent requirements for licensure, stronger penalties, and due diligence requirements. Most comments stated that the full adoption of revised NABP model rules would improve security nationwide, and that stricter uniform standards were desirable across all 50 states so as not to create 50 different sets of criteria and rules for licensing. FDA was encouraged to revisit the current minimum standards requirements described in 21 CFR Part 205 to assess whether a "Federal floor" for states would enhance or diminish state efforts to meet the NABP recommendations. A detailed discussion of the comments is in Appendix B.

(3) Discussion

FDA is pleased to recognize the recent efforts by NABP in revising the Model Rules. The revised Model Rules significantly strengthen the requirements for licensure, as well as put in place or fortify requirements that will ensure and protect the integrity of drug products as they travel through the U.S. drug supply chain from the manufacturer to the consumer.

NABP sought comment from FDA, as well as interested stakeholders, in developing the revised Model Rules. The comments that FDA received as part of the anti-counterfeiting initiative have been discussed with NABP.

The revision of the Model Rules sought to enhance the protections included in the original version of the Model Rules and close existing gaps. The table below contains highlights of the revised Model Rules:



NABP is taking steps to facilitate implementation of the revised Model Rules, including: (1) publishing a list of susceptible products and calling for a coalition of national organizations to develop a process to maintain and update the list; (2) serving as bondholder for wholesalers in order to consolidate the need to hold a bond in all states where a wholesaler may do business; and (3) establishing a clearinghouse that will list wholesalers who receive accreditation by NABP and who have passed an inspection by their newly created inspection service, which NABP will conduct in partnership with the states. FDA supports NABP's efforts to facilitate adoption and implementation of the enhanced Model Rules.

Counterfeiting is a problem that is not isolated to one state. If a state strengthens its licensing requirements while a bordering state does not, the counterfeiters and illegitimate wholesalers will likely move into the bordering state. Widespread state adoption, implementation, and enforcement of the Model Rules would help combat counterfeiting.

(4) FDA Conclusion:

Because States have an important role in regulating drug distributors, adopting and enforcing stronger state anti-counterfeiting requirements would help in our collective effort to detect and deter counterfeiting.

—FDA strongly supports the efforts taken by NABP to enhance the Model Rules and other actions taken to facilitate implementation;

—FDA supports all efforts by the States to adopt these Model Rules. Adoption of the model rules by all States would have a significant impact on protecting the Nation's drug supply by ensuring that all persons and entities involved in wholesale distribution of drug products meet stringent licensing criteria and maintained high ethical and business standards;

—FDA encourages these state actions and the agency intends to explore whether and to what extent to revise the current minimum standards for state licensing of wholesale prescription drug distributors in 21 CFR Part 205.

C. Higher Penalties for Drug Counterfeiting

(1) What FDA sought comment on:

Discuss the advantages and disadvantages of increased penalties for counterfeiting drugs

(2) What the Comments Said:

There was overwhelming support and unanimous agreement that higher penalties for counterfeiting are needed.

(3) Discussion:

FDA agrees with comments suggesting that higher penalties deter drug counterfeiters.

Current sentencing guidelines for counterfeit drug distribution are not commensurate with the public health threat posed by this criminal activity and strengthening the guidelines should help deter such conduct in the first instance. Despite the significant threat to public health posed by counterfeit drug products, current law provides penalties far below the level of some purely economic crimes. For example, counterfeiting a prescription drug label (bearing a registered trademark) is punishable by up to 10 years in prison, while counterfeiting the drug itself is punishable by a maximum of only 3 years in prison. Therefore, FDA plans to continue to pursue its request that the United States Sentencing Commission consider amending the sentencing guidelines to substantially increase criminal penalties for manufacturing and distributing counterfeit drug products and to specifically provide for enhanced penalties based on the level of risk to the public health involved in the offense.

(4) FDA Conclusion

FDA intends to pursue its request that the United States Sentencing Commission consider amending the sentencing guidelines to increase substantially criminal penalties for manufacturing and distributing counterfeit drugs and to provide specifically for enhanced penalties based on the level of risk to the public health involved in the offense.

3. Creation of a Counterfeit Alert Network for Information Dissemination and Education

(1) What FDA sought comment on:

Whether a counterfeit alert network should be created through use of existing, or newly developed, communication tools, that allow reception, dissemination, and sharing of information about counterfeit drugs in a timely manner;

What are the capabilities of current communication network, what a communication network should have in order to part of a counterfeit alert network, and costs associated with developing or adapting current systems.

(2) What the Comments Said:

The agency received many comments supporting the creation of a counterfeit alert network. Most of the comments suggested that the agency take steps to build on existing networks and several comments offered their organizations' distribution lists or network as a conduit for the counterfeit alert network. The agency was advised that the counterfeit alert network should not be overused in order to avoid alert "fatigue," which could create indifference or doubt regarding the importance of the messages. The agency was encouraged to consider cost-effective public/private partnerships to design communication strategies and facilitate efforts to standardize anti-counterfeit communications and to augment and coordinate communication systems. A detailed discussion of the comments is in Appendix B.

(3) Discussion:

The FDA is committed to informing the public, particularly consumers, pharmacists, other health professionals, wholesalers, and others involved in the U.S. drug distribution system, about counterfeit drug incidents in a timely manner. FDA is also committed to educating them about ways to identify and prevent counterfeits from entering into this system. To increase awareness of counterfeit drugs and safeguard the Nations drug supply, FDA is creating a network of national organizations, consumer groups, and industry representatives to deliver time-sensitive messages and information about specific counterfeit incidents and educational messages about counterfeits in general. The network is called the "Counterfeit Alert Network."

Partners in the Counterfeit Alert Network will be required to enter into a co-sponsorship agreement with FDA that lays out roles and responsibilities. Partners agree to disseminate the FDA time-sensitive messages to their members/subscribers/readers in the manner outlined in the co-sponsorship agreement, to partner in delivering educational messages, and in the case of health professionals, provide a link to the MedWatch website to report suspect counterfeits. A copy of the co-sponsorship agreement can be found in Appendix C.

The agency plans to maintain a list (as it does now) of additional health professional, consumer, and industry organizations, and media outlets to notify when an actual counterfeit incident is confirmed and what steps to take to minimize risks and remove the product from the U.S. distribution system. This will help ensure the widest possible distribution to the appropriate audience's.

FDA met with consumer groups, pharmacy groups, and physician groups to determine the type of information that would be most useful to receive from FDA in the event of a counterfeiting incident. FDA intends to create templates for standardizing the format and content of health professional and consumer information in the

event of a counterfeit incident that can guide outreach efforts in an efficient manner, while assuring the flexibility FDA needs to formulate the messages.

(4) FDA Conclusions:

FDA will create a Counterfeit Alert Network that links together and enhances existing counterfeit notification systems, to provide for timely and effective notification to health professionals and consumers of a counterfeit event.

—FDA is creating a counterfeit alert network to partner with national healthcare organizations, consumer groups, and industry representatives to deliver time-sensitive messages about specific counterfeit incidents and educational messages about counterfeits in general, and information about how and when to report suspect counterfeit drug products;

—FDA plans to develop and execute multi-media informational strategies for specific audiences to ensure that the messages reach the largest number of interested people possible through the network;

—FDA plans to develop internal guidelines for the informational contents of outgoing FDA messages that will bemost useful to communicate a counterfeiting incident to individual stakeholder groups.

4. Health Professional Reporting Encouraged via MedWatch

(1) What FDA sought comment on:

Whether FDA's MedWatch system should be used as a tool to receive and disseminate timely information about counterfeit drug products, especially identification of suspect drug product?

(2) What the Comments Said:

Most of the comments supported the use of MedWatch for reporting suspect counterfeit drugs. These comments stated that health professionals are familiar with MedWatch and it would be too cumbersome and expensive to develop a new system, which people would have to be educated to use. One comment believed that reports of possible counterfeiting should be separate from MedWatch because it is not designed for criminal activity reporting and oversight. Another comment stated that because MedWatch is a voluntary reporting system, there could be significant under-reporting.

(3) Discussion:

For nearly 10 years, MedWatch has been FDA's reporting portal for adverse drug reactions and "product problems." These include problems with product quality that may occur during manufacturing, shipping, or storage, such as product contamination, defective components, poor packaging or product mix-up, questionable stability, and labeling concerns. If a pharmacist or consumer notices an unexplained change in size, shape, color, or taste of their dosage form, or notices that the coating is chipped or tablets are cracked, or that the drug is not working like it usually does, they may consider that to be a problem with their product. These are also characteristics that could occur if the product was a counterfeit drug. In fact, in the past, FDA has received some reports of suspect counterfeit drugs through MedWatch.

If a consumer suspects that his or her medicine is counterfeit, they are encouraged to contact the pharmacist who dispensed the drug, rather than report directly to MedWatch. The pharmacist may have information from the manufacturer that the shape, color, or taste of the product may have changed, or other information that may be helpful in determining if the product may be counterfeit or if the suspicious characteristic of the product or its packaging is expected.

The use of MedWatch is for health professional reporting. This would not affect the agreement with the Pharmaceutical Research and Manufacturers of America (PhRMA), whereby manufacturers have agreed to report counterfeits of their products to FDA's Office of Criminal Investigations, within 5 days of becoming aware of the counterfeit.

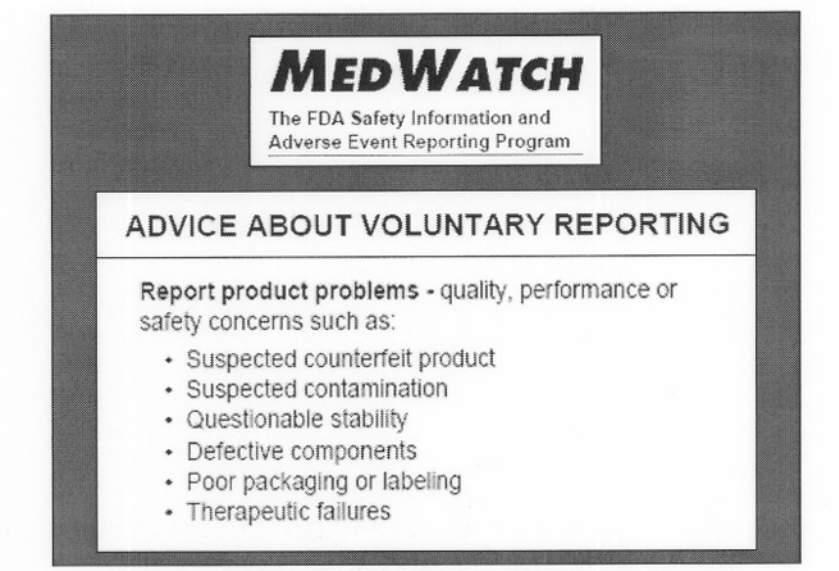
FDA has streamlined procedures for processing reports of suspect counterfeit drugs. The MedWatch Central Triage Unit (CTU) standard operating procedures (SOPs) have been amended to include "suspect counterfeit product" as a category of reports, so the CTU will know where to send the report for expedited processing.

It is easy and convenient to file a report with MedWatch. All reports are confidential and the identity of the reporter is not disclosed. FDA encourages reporting using the online reporting form that can be found at *www.fda.gov/medwatch.*

(4) FDA Conclusion:

FDA plans to encourage and educate health professionals to report suspect counterfeit drugs to MedWatch.

—FDA plans to encourage and educate health professionals to report suspect counterfeit drugs to MedWatch as an overarching mechanism to report such information;
—FDA plans to change the instructions for the MedWatch reporting form, both paper and online versions, so reporters will know how and when to report suspect counterfeits. Additionally, FDA plans to amend the MedWatch website description of product problems to include suspect counterfeits.



Change made to the instructions on the MedWatch reporting form.

5. Secure Business Practices

(1) What FDA sought comment on:

Whether to develop sets of "secure business practices" which would be voluntarily adopted by manufacturers, wholesalers, re-packagers, and pharmacies?

Whether stakeholders should designate an individual or team to coordinate security and anti-counterfeiting activities?

Issuance of an FDA guidance document concerning physical site security and supply chain integrity?

There was no proposal specific to re-packagers. However, FDA identified independent re-packaging operations, through several ongoing investigations, as a point of entry for counterfeit drugs into the distribution system, and some of the proposed options would have had the effect of limiting those re-packaging operations.

(2) What the comments said:

The comments supported the need for development of secure business practices by all stakeholders in the drug distribution chain because each stakeholder has a responsibility to ensure that pharmaceutical products are authentic. The comments suggested that such practices include ensuring the legitimacy of business partners and refusing to do business with persons of unknown or dubious background, taking steps to ensure physical security, and identifying an individual or team in the organization with primary responsibility for ensuring that effective security practices are implemented.

It is critically important that the physical facilities involved in the production, distribution, or dispensing of pharmaceuticals are secure against counterfeit drugs. In the area of food safety, our Center for Food Safety and Nutrition (CFSAN) has issued guidance for the food industry on preventive measures that establishments may take to minimize the risk that products under their control will be subject to tampering or other malicious, criminal, or terrorist actions.

Although it was acknowledged that re-packagers were required to comply with Current Good Manufacturing Practices as set forth in 21 CFR 210 and 21 CFR 211, due to the involvement of re-packaging operations in some recent counterfeiting schemes, FDA was asked to provide more oversight and to conduct more frequent inspections of re-packagers.

See Appendix B for a detailed discussion of actions taken by manufacturers, wholesalers, and pharmacists to develop secure business practices.

(3) Discussion:

Recent counterfeiting cases demonstrate that the current business practices of participants in the U.S. drug distribution system are in some cases inadequate to prevent the introduction of counterfeit drugs. Implementation of secure business practices by participants in the U.S. drug supply chain is critical for deterring and detecting counterfeit drugs. Therefore, FDA commends and strongly supports efforts to develop and implement secure business practices for these participants. FDA plans to facilitate and encourage the development of innovative approaches to securing business transactions in the drug supply chain. The number of stakeholders who have told FDA they are already implementing the business practices discussed above is very encouraging. In addition to identifying effective security measures, the designation of an individual or team to have primary responsibility for coordinating security activities helps ensure effective implementation.

FDA agrees that re-packaging operations can be a significant vulnerability in the drug supply chain. Although current statutory and regulatory requirements allow for appropriate oversight of re-packagers, FDA agrees that enforcement of those requirements could be strengthened.

(4) FDA Conclusions:

For government efforts against counterfeit drugs to be successful, drug producers, distributors, and dispensers will have to take effective actions to secure their business practices.

—Efforts by stakeholders to develop the secure business practices listed above would help protect the public health and diminish counterfeiting;

—FDA plans to work with individual stakeholders and groups representing stakeholders, as necessary and appropriate, to continue to develop, make publicly available, and widely disseminate secure business practices;

—Good security practices include designation of an individual or team, reporting directly to the organization's senior management, to coordinate the security and anti-counterfeiting activities for the organization;

—FDA supports efforts by pharmaceutical manufacturers, wholesalers, and retailers to secure their physical facilities against counterfeit drugs. FDA plans to issue guidance on physical site security that applies to participants in the U.S. drug distribution system.

—FDA plans to make its oversight over re-packagers of drugs a higher priority. FDA expects to increase the frequency with which it inspects re-packagers whose operations are found to be at increased risk for the introduction of counterfeit drugs. The increase in frequency will be based on the degree of risk, as determined by applying to re-packaging operations the risk based model FDA is developing for prioritizing inspections of drug manufacturing sites.

6. FDA'S Rapid Response to Reports of Suspect Counterfeit Drugs Streamlined

(1) What FDA sought comment on:

Enhancing FDA's internal processes for responding to and investigating reports of suspected counterfeit products

(2) What the Comments Said:

The comments unanimously supported any efforts by the agency to rapidly respond to reports of suspect counterfeit drugs.

(3) Discussion:

FDA takes reports of suspect counterfeit products very seriously. The agency is proud of its investigative tools and talents and its quick response to the public health needs when a counterfeit has been reported and has been confirmed. To improve this process, the agency evaluated its policies and procedures for responding to reports of counterfeit drugs to determine if FDA's response could be more efficient. Although FDA has had many positive experiences in responding and working with manufacturers and the public, FDA identified several ways to further enhance coordination and communication among all initial responders within the agency.

Because different parts of the agency throughout the country may receive the potential counterfeiting report, in some instances, it may take time for the information

to flow to the appropriate people who need it to respond efficiently. Therefore, FDA has established an FDA-wide rapid response protocol for suspect counterfeit drugs that will ensure that specified persons/offices/divisions within the agency are notified and engaged as soon as possible after the report is made to the agency. Policies and procedures have been or will be amended to reflect this streamlined information flow and coordination of agency response. Increased coordination and communication will help FDA to initiate rapidly any criminal or civil investigation, as well as to assess the health hazard of the counterfeit situation so the public health response can be launched.

(4) FDA Conclusion:

To respond rapidly to a report of a suspect counterfeit, FDA is further streamlining its internal processes to respond quickly to reports of suspect counterfeit drugs by improving coordination and communication among all initial responders in the agency.

—FDA intends to amend its internal SOPs, where appropriate, to provide for more rapid response when a suspect counterfeit is reported;

—FDA intends to build on lessons learned from working with manufacturers in past counterfeiting experiences to determine how industry/agency collaboration can and should be strengthened.

7. Educating the Public and Health Professionals

a. Consumers

(1) What FDA sought comment on:

As the sophistication of the "final product" drug counterfeiting operations has increased, the public needs to be more aware of ways to identify the risk of counterfeit drugs, receive instructions on ways to minimize the chance of receiving fake products and to identify potential counterfeits.

(2) What comments said:

The comments stated that it is imperative that consumers be encouraged to be more proactive in managing their health and be given useful tools to be vigilant to help avoid potential counterfeit drugs. Consumers should be educated to be aware of noticeable differences in their medication, the packaging, or any adverse events. In addition, consumers should understand the important role that their pharmacist and healthcare providers can play in identifying, reporting, and responding to counterfeit drug events. However, the comments warned that care should be taken in any education campaign to not unnecessarily alarm the public.

(3) Discussion:

Despite the growing sophistication of counterfeit drug threats, many consumers are not fully aware of these risks. The Agency, in conjunction with consumer and patient advocates, as well as industry representatives is eager to find additional creative ways to educate the public of the potential threat of counterfeit drugs. The messages should alert consumers to the risk, offer ways consumers can recognize the signs of a potentially counterfeit product, teach them how to reduce the risk of exposure and tell them what to do if they suspect they have encountered one. Of course, FDA wants to strike an appropriate balance in the need to proactively educate consumers without causing unnecessary alarm that could interfere with their use of prescribed drug regimes. Most important, it is critical to focus awareness, and education programs should focus on issues that consumers can control.

FDA has an ongoing educational campaign that is intended to educate consumers about the risks of buying medicines online. FDA intends to reaffirm this message and focus the educational campaign on teaching safe purchasing methods. Particular focus will be placed on encouraging the public to seek out the Verified Internet Pharmacy Practice Site (VIPPS) seal when purchasing from an online pharmacy.

In addition, stakeholders indicated that there is a need for better, timelier, accurate information about specific counterfeit situations. FDA plans to create a counterfeit drug resource page on our website. The objective of this webpage is to concentrate customized education tools into a resource library that can empower individual stakeholder groups.

(4) FDA Conclusions:

Educating the consumers about the risks of counterfeits is a critical piece in the effort to stop counterfeits from entering the stream of commerce.

—FDA plans to develop additional, multi-layer, consumer-oriented educational materials that will help them learn about counterfeits, what to watch for, and

where to turn for useful information if they think they have encountered a suspected counterfeit;

—FDA plans to re-launch the FDA public service announcement (PSA) campaign for best online buying practices to educate consumers about how to buy drugs online safely, and risks to avoid in online purchasing;

—FDA plans to house on its *www.fda.gov* website a comprehensive, consumer-friendly online library that will contain both general and specific counterfeit drug information. It will also contain targeted educational materials for various interest groups that discuss counterfeit issues generally. In addition, the agency intends to develop a new FDA anti-counterfeiting resources icon to increase familiarity with the issue.

b. Pharmacists and Other Health Care Professionals

(1) What FDA sought comment on:

Pharmacists need improved tools to receive information and to educate themselves about how to handle these situations and to keep abreast of current counterfeit events. They need to know how to identify and counsel consumers who might have received counterfeit products.

Physicians, nurses and other health professionals also have contact with consumers taking pharmaceuticals and can help identify and counsel patients that could have accessed a counterfeit. This will require these groups keep up to date on current counterfeit events and know steps to take to report situations if a counterfeit is suspected.

(2) What the comments said:

Groups representing pharmacists and pharmacies recognize the need for pharmacists to take a leadership role in the identification of counterfeits, prevention of their introduction into the distribution chain, and education of consumers about counterfeits.

The healthcare community indicated that awareness and education campaigns are important if its health professionals are to be active participants in the fight against counterfeit drugs.

(3) Discussion:

Pharmacists and health professionals can play a major role in helping identify counterfeits and preventing their introduction into the distribution chain. FDA has been working with pharmacy and medical professional groups to develop educational materials for pharmacists and other healthcare professionals, including doctors, nurses, and physician assistants.

(4) FDA Conclusion:

FDA plans to enhance its educational programs for pharmacists and other health professionals about their role in minimizing exposure to, identifying, and reporting counterfeits.

—FDA intends to work with pharmacy and health care professional groups to develop materials to help educate their profession on the risk of counterfeits, what to do in case a counterfeit is suspected and ways to aid in educating consumers. This will include development of clear, concise messages and protocols, as well as the establishment of a delivery mechanisms that will help them learn about the threat of counterfeits, what to watch for, and where to turn for useful information in the case of a suspected counterfeit;

—FDA intends to encourage pharmacy and health care professionals to become partners in the agency's newly established Counterfeit Alert Network;

—FDA intends to expand its outreach efforts by presenting at or participating in conferences and by publishing articles in professional journals and periodicals that target audiences of doctors, nurses, pharmacist and hospital administrators to educate them about counterfeits and raise awareness of the risks;

—FDA intends to work with health professional trade groups to identify or improve data collection/reporting systems that could help identify counterfeits as they enter the stream of commerce (i.e, include appropriate questions on the ER patient admission questionnaire that might help diagnose usage of a counterfeit drug.)

8. International Approach

(1) What FDA sought comment on:

Strengthening international cooperation in law enforcement efforts, identifying counterfeit products, using anti-counterfeiting technologies, and educating stakeholders and consumers

Whether there should be global standards for packaging of pharmaceuticals and the use of anti-counterfeiting technologies

(2) What the comments said:

The comments supported FDA involvement in global efforts to deter and detect counterfeit drugs.

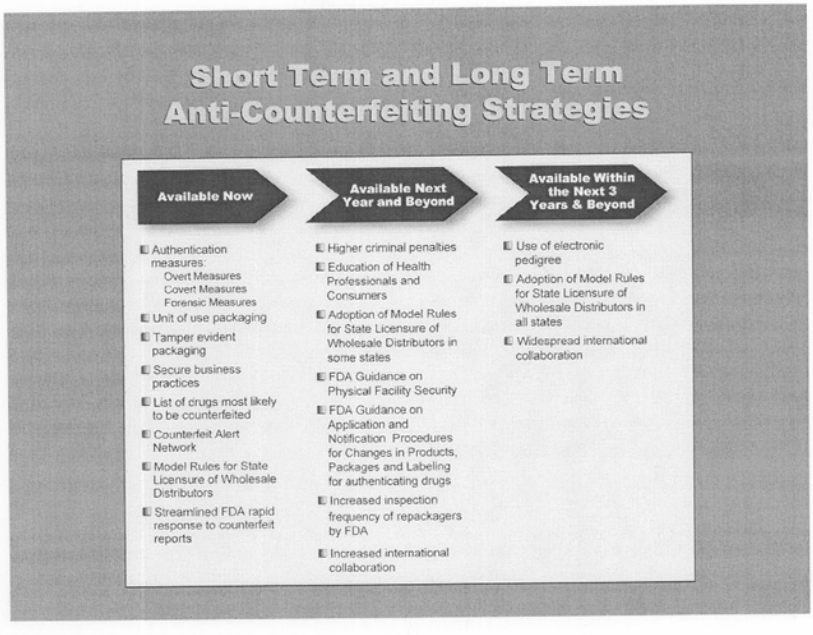
(3) Discussion:

The growing global prevalence of counterfeit drugs must be curtailed. The steps described in this report are intended to secure the U.S. domestic drug supply. However, as long as counterfeit drugs exist worldwide, opportunities could arise for counterfeit drugs to find their way into the United States. Many countries have taken steps to secure their Nation's drugs supply, while others struggle because of limited resources, inadequate regulatory infrastructure, or competing national health priorities. The World Health Organization (WHO) has taken the lead to increase worldwide collaboration and to develop strategies to deter and detect counterfeit drugs. There are several international criminal enforcement collaborations, such as the Permanent Forum on International Pharmaceutical Crime and the Interpol Intellectual Property Crimes Action Group. FDA intends to work with WHO and other international organizations to develop and implement worldwide strategies to combat counterfeit drugs.

(4) FDA Conclusions:

FDA will collaborate with foreign stakeholders to develop strategies to deter and detect counterfeit drugs globally.

Below is a table showing when certain anti-counterfeiting measures will be available:



APPENDICES

Appendix A: Counterfeit Alert Network Co-sponsorship Agreement

Appendix B: More detailed description of the comments received for certain issues (where the comments were diverse or lengthy)

APPENDIX A

COUNTERFEIT ALERT NETWORK CO-SPONSORSHIP AGREEMENT

Background

The U.S. Food and Drug Administration (FDA) is committed to informing the public, particularly consumers, pharmacists, other health care professionals, wholesalers, and others involved in the U.S. drug distribution system, about counterfeit drug incidents in a timely manner and educating these parties on ways to identify and prevent counterfeits from entering into this system. To increase awareness of counterfeit drugs and safeguard the Nations drug supply, FDA will create a network of national organizations, consumer groups, and industry representatives to deliver time-sensitive messages and information about specific counterfeit incidents and educational messages about counterfeits in general. FDA also will develop and execute informational strategies for specific audiences to ensure that the messages reach the largest number of interested people possible through the network. The network will be called the "Counterfeit Alert Network."

The goals of the Counterfeit Alert Network include, but are not limited to:

—disseminating alert messages to a wide audience about specific counterfeit drug incidents in the United States and measures to take to minimize exposure (e.g., recall information);

—outlining the roles and responsibilities of consumers, pharmacists, other health professionals, and wholesalers must play to identify counterfeit drugs, report suspect counterfeit drugs, and prevent them from entering the U.S. distribution system; and

—developing a network of national organizations, consumer groups, and industry representatives to help disseminate the information.

[INSERT CO-SPONSIOR ORGANIZATION INFORMATION]

Importance of the Partnership to FDA and [Organization]

This partnership will increase the potential audience of FDA's important notifications about specific counterfeit drug incidents and messages about how and when to report suspect counterfeit drugs. By distributing FDA developed messages through the [ORGANIZATION] information system, these messages can reach more than [#] people.

Responsibilities of FDA and [Organization]

FDA will develop targeted messages, with a particular focus on consumers, pharmacists, and other health care professionals when a counterfeit drug is found in the U.S. distribution system. FDA will also develop educational and informational materials about how to detect a counterfeit drug, what to do if a drug is believed to be counterfeit, how to report the suspect counterfeit to the FDA, and ways to minimize the risk of receiving a counterfeit drug. These materials may include: web-based documents, print ads, posters, prepared newspaper articles, fact sheets, consumer brochures/pamphlets, and informational packets. FDA will provide any logistical and technical support, such as writing, layout, designing, and preparing illustrations for the products.

FDA will ensure that all materials are cleared through the Agency and the U.S. Department of Health and Human Services before releasing material to the [ORGANIZATION] for public distribution FDA will provide these materials in a format (hard copy, digital, or electronic) that [ORGANIZATION] can use, as appropriate, to create, manufacture, and/or have printed in enough quantities to distribute to various audiences. FDA will not be responsible for any costs outside of the materials already produced by FDA.

[ORGANIZATION] will distribute in a timely manner FDA's notifications about specific counterfeit incidents as an alert through an active messaging system (separate email or fax alert correspondence). [ORGANIZATION] will facilitate the ability of their members/subscribers/website visitors to report suspect counterfeit drug products to FDA, e.g., via a link to the FDA Counterfeit Drugs webpage or FDA's MedWatch webpage. [ORGANIZATION] will distribute relevant FDA-educational messages about counterfeits, covering such issues as awareness, recognition, prevention, tracking, and authentication of drug products.

The [ORGANIZATION] will pay for the cost, if any, of printing materials, posting materials on its website, email distribution, renting ad space, and securing print placement in magazines and newspapers, as appropriate. [ORGANIZATION] will make clear, in any solicitation for funds to cover its share of the distribution costs that it, not FDA, is asking for the funds. [ORGANIZATION] will not imply that FDA endorses any fundraising activities in connection with the event. [ORGANIZA-

TION] will make clear to donors that any gift will go solely toward defraying the expenses of [ORGANIZATION], not FDA.

FDA and the [ORGANIZATION] I will develop a dissemination plan that outlines where and how the educational materials and alert messages about specific counterfeit incidents will be distributed to various audiences.

FDA and the [ORGANIZATION] will review this agreement in 2 years from the original date of this agreement, but either party to this agreement can terminate its participation at any time by notifying the other party of its intent to do so in writing.

Charges

The [ORGANIZATION] will not sell any educational materials related to this joint effort. [ORGANIZATION] will not impose an enrollment or registration fee for subscribers to receive this information.

Independently Sponsored Portions and Endorsements

All materials and efforts related to the Counterfeit Alert Network will be jointly sponsored. FDA staff will not be used to develop, promote, or otherwise support any event that is independently sponsored by the co-sponsor, although official announcements and brochures may contain factual references to the available materials and Counterfeit Alert Network messages.

The [ORGANIZATION] will not use the name or logo of FDA except in factual publicity. Factual publicity includes materials provided to [ORGANIZATION] on FDA's program and Counterfeit Alert Network materials. Such factual publicity shall not imply that the involvement of FDA serves as an endorsement of the general policies, activities, or products of the [ORGANIZATION]. Where confusion could result, a disclaimer should accompany publicity to the effect that no endorsement is intended. The [ORGANIZATION] will clear all publicity materials with FDA to ensure compliance.

Records

Records concerning this partnership shall account fully and accurately for any financial commitments and expenditures of FDA and [ORGANIZATION]. Such records shall reflect, at a minimum, the amounts, sources, and uses of all funds.

Public Availability

This co-sponsorship agreement, as well as any financial records for this partnership, shall be publicly available.

Co-Sponsorship Guidance

FDA and the [ORGANIZATION] will abide by the memorandum of August 8, 2002, "Co-sponsorship Guidance," issued by the Associate General Counsel for Ethics.

APPENDIX B

EXPANDED DESCRIPTION OF COMMENTS RECEIVED

Technology

Unit of Use Packaging

Comments supporting widespread utilization of unit of use technology cited:

—The decreased need for repackaging which is a point of entry for counterfeit drugs;

—Authentication technologies applied by the manufacturer would reach the dispensing pharmacy and the patient;

—The lower cost for utilizing unit of use packaging on newly approved drugs;

—The deterrent value to counterfeiters of the higher costs of duplicating unit of use packages;

—Improvement in patient safety due to reduction in dispensing errors and better patient compliance; and

—Increased pharmacist availability for patient counseling (due to reduction in time needed to fill prescriptions).

Some comments cautioned the FDA against mandating unit of use packaging for all drugs citing:

—The high cost, and length of time, it would take to change production lines from bulk to unit of use packaging;

—The investment made by many pharmacies in re-packaging and pill counting equipment;

—The difficulty of packaging certain products (e. g. vaccines, multi-dose liquid formulations) in unit of use form;
—The need to differentiate repackaging performed under contract to a manufacturer or by a pharmacy (which may achieve market efficiencies) from repackaging by other entities;
—The need to perform a careful product-by-product cost-benefit analysis on unit of use packaging before creating any requirements;
—The minimal hurdle that unit of use packaging creates for sophisticated drug counterfeiters;
—The need to comply with the Consumer Product Safety Commission (CPSC) regulatory requirements for child resistant unit of use packaging;
—The difficulty some consumers (e.g., arthritic patients) may have in opening unit of use packaging such as some blister packs;
—The need for pharmacists to modify prescribed quantities to correspond with available unit of use packages which could require changes in state law; and
—The need to establish standards for such things as size and shape of unit of use packaging in order to minimize patient confusion and address shelf space issues.

Authentication Technologies

They supported use of authentication technologies as part of an overall anti-counterfeiting strategy and stated that authentication technologies serve two purposes:
They make it more difficult and expensive to produce a copy of the drug or its packaging and labeling, and
They provide a means for determining if a specific drug, package, or label is authentic.

Manufacturers of specific anti-counterfeiting technologies provided us with descriptions of their products that were extremely valuable in helping us understand how they work, their cost, and how they might be incorporated into pharmaceutical products, packaging, and labeling or used to detect counterfeit products through forensic and other analytical methods, including rapid methods.

Many comments supported the issuance of an FDA guidance document on the use of authentication technologies. They stated that there was no clear FDA policy specifically targeted to this important subject. They suggested that current FDA policies and practices for New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and Biologics License Applications (BLAs), supplements, and other notification procedures should be clarified so the policies and procedures applicable to use of anti-counterfeiting technologies are clearly articulated and available in a single document.

The following points were made regarding the use of authentication technologies on drug products, their packaging and labeling:
—There is no "silver bullet" solution—all anti-counterfeiting technologies can be defeated;
—Because all anti-counterfeiting technologies can be defeated, a more extensive approach utilizing layered overt and covert technologies that are changed on a regular basis is frequently required;
—Authentication technologies are expensive;
—Manufacturers should determine which authentication technologies to use, on a product specific basis. The FDA should not require the use of any specific anti-counterfeiting technology. For example: the number and type (e.g., overt, covert) of technologies utilized for a given product need to take into account the type of product (e.g., solid, liquid), use, cost, history of counterfeiting etc.;
—Repackaging destroys anti-counterfeiting technologies employed by the manufacturer;
—Incorporation of anti-counterfeiting measures into the product, packaging, and labeling may be subject to application and notification requirements which means that initiating or changing such technology could require a significant time and expense;
—Although all products are at risk for being counterfeited there is a need to develop criteria or a classification system to help identify those products at highest risk for being counterfeited and thereby assist stakeholders in identifying products that might derive a greater benefit from the incorporation of authentication technologies;
—The large number of available technologies coupled with the number of different products stocked in pharmacies and the need to change anti-counterfeiting measures make it difficult for pharmacists to be knowledgeable about the technologies used for a product at any given time;

—Technologies that do not allow for "real time" or consumer authentication (e.g., covert technologies known only to the manufacturer and/or the FDA) may have an uncertain benefit in rapid identification of counterfeit drugs.

List of Drugs Likely to be Counterfeited

Many comments stated that it was important for stakeholders to allocate financial resources to protect those products that are most likely to be counterfeited. There was agreement that the criteria we suggested to identify drugs that were likely to be counterfeited were correct. These included:

—Impact on public health if the drug were counterfeited;
—Drugs history of counterfeiting;
—Drugs price;
—Drugs volume;
—Drugs dosage form;
—Drugs clinical uses; and
—Whether similar products had a history of being counterfeited.

However, there was no consensus on how to apply these, or other, criteria in creating a list of such products.

As stated above, some comments suggested that instead of developing a list of drugs likely to be counterfeited, a set of criteria for determining whether a drug was at likely to be counterfeited should be created. One proposal for such criteria was:

A drug has been subjected to a seizure or stop sale notice because of counterfeiting, or

There is documentation that a drug was counterfeited and is the subject of an investigation by Federal or State authorities AND

The product is high cost (e.g., over $200 per dose) or high volume (e.g., top fifty drugs), or

The product is used extensively for treatment of HIV/AIDS or cancer, or

The product is injectable, or

The product distributed in a special or limited way, or

There are multiple documented instances of pedigrees not being passed with the product

Radiofrequency Identification Technology

We received a large amount of information on the benefits, costs, and unresolved issues relating to RFID. These include:

Benefits
—Ability to deter and detect counterfeit drugs;
—Ability to conduct efficient targeted recalls;
—Ability to manage inventory;
—Ability to identify theft;
—Ability to identify diverted drugs; and
—Improvement in patient safety by assuring correct dispensing of drugs.

Costs
—Purchasing hardware (e.g., tags, readers) and software;
—Integration into legacy information systems;
—Database creation, security, and maintenance;
—Integration of RFID technology into existing manufacturing processes, distribution procedures;
—Compliance with regulatory requirements (e.g., cGMP, notification, product integrity); and
—Feasibility studies.

Unresolved Issues
—Need for all stakeholders to embrace the technology in similar timeframes in order to realize the full potential of RFID technology including provision of a universal electronic pedigree;
—Need to develop standards and business rules;
—Need to address database issues such as structure (e.g., central vs. distributive), ownership, access, and security;
—Clarification of regulatory requirements pertaining to use of RFID (e.g., cGMP, electronic records, notification); and
—Need for a flexible migration path to the use of RFID in order to meet the needs of different stakeholders.

Stakeholder Activities

We have been informed of several feasibility studies, starting in early 2004, that should give members of the supply chain experience using RFID as well as provide them with an opportunity to test its business uses and identify potential barriers to its acceptance. These studies include:

—*Wal-Mart.*—Drug manufacturers and wholesalers will attach RFID tags to all bottles of controlled substances;
—*Accenture.*—Coordinating a study of RFID involving manufacturers, wholesalers, and retailers that will explore the use of RFID for tracking, tracing, recalls and theft of selected pharmaceuticals;
—*CVS.*—Is studying the potential benefits that tagging and tracing pharmaceuticals and prescriptions in a retail pharmacy would have on operating efficiency, quality of patient care, and customer service; and
—Other feasibility studies using RFID are being planned in Europe to study the use of serialization for authentication at the point of dispensing.

In addition to feasibility studies, we understand that several groups representing many supply chain participants have been meeting to discuss ways to facilitate the adoption of RFID. For example the Product Safety Task Force (PSTF) convened under the auspices of the Healthcare Distribution Management Association (HDMA) is developing business requirements and identifying business issues relating to RFID technology.

The PSTF and other stakeholders have informed us that the migratory path (or phase in) to widespread use of RFID at a package level could vary by stakeholder based on the place of that stakeholder in the supply chain (e.g., manufacturer vs. retailer) and on specific costs and benefits accruing to that stakeholder (e.g., types of products manufactured, number of distribution centers, technology cost per product).

Several migratory paths were mentioned, including:
—Phasing in use of RFID technology with use at the case and pallet preceding use at the package level;
—Phasing in use of RFID technology starting with use on pallets, cases, and packages of "high risk" products with gradual inclusion of other products at all levels; and
—Use of RFID technology at the pallet and case level coupled with use of 2–D Bar Codes at the package level with gradual phase in of RFID technology at the package level.

According to stakeholders, these paths are not mutually exclusive and it is likely all of these, and other, paths will be utilized as RFID technology becomes more widely adopted.

Secure Business Practices

Below are some of the secure business practices that have been developed by participants in the U.S. drug distribution system.

Manufacturers

Several manufacturers have announced policies intended to secure the supply chain. These policies include:
—Limiting sales to authorized wholesalers. Authorized wholesalers are defined either as wholesalers who purchase a manufacturers products exclusively from that manufacturer or as wholesalers who purchase a manufacturers product directly from the manufacturer or from other authorized wholesalers;
—Making the list of authorized distributors publicly available;
—Ability to audit the sales records of wholesale distributors;
—Working with dispensing pharmacies to ensure they are aware of the identities of authorized distributors; and
—Designation of an individual or team to coordinate security and anti-counterfeiting activities.

Wholesalers

The Healthcare Distribution Management Association (HDMA) released a document entitled "Recommended Guidelines for Pharmaceutical Distribution System Integrity" which set forth a series of recommended actions for wholesalers to take prior to and while conducting business transactions with other wholesalers. In essence they comprise a "due diligence" checklist which includes items such as:
—Obtaining detailed information about the wholesalers licensure, inspection results, history of disciplinary actions, corporate officers, owners, and management personnel;
—Performing a criminal background check on the wholesaler, its officers, owners, and other key personnel;
—Obtaining a credit history and information about its business activities, financial status, and liability insurance;
—Performing a detailed physical site inspection; and

—Ensure that the wholesaler is in compliance with Federal and State requirements, verifies that the wholesaler is an authorized distributor for the products being transferred or has a process in place for verifying pedigrees.

Individual wholesalers supported the HDMA guidelines and provided FDA with ideas for additional secure business practices including:

—Not selling pharmaceuticals to other wholesalers at all; and

—Completely separating the functions of quality assurance and compliance from sales and marketing and requiring quality assurance and compliance staff to perform due diligence on potential business partners.

Pharmacies and Pharmacists

We have been informed that several organizations representing pharmacies and pharmacists are developing secure business practices as a guide for pharmacies and pharmacists. One pharmacy group notified us that they have already published a list of strategies to use for assuring the integrity of pharmaceuticals. This list includes:

—Staying informed about reports of counterfeit drugs;

—Contacting wholesalers to get information about the status of their licensure, whether they are authorized distributors, and where they source their drugs;

—Evaluate pharmacy security;

—Educate hospital staff;

—Follow up on patient complaints; and

—Report suspect products.

Prescription Drug Marketing Act (PDMA)

A majority of the comments that discussed PDMA noted the limitations and concerns of full implementation of PDMA. Such limitations include:

—Paper pedigrees can be forged and counterfeited;

—Paper pedigrees are logistically difficult to accommodate in the drug distribution system;

—ADRs are not required to pass pedigree information on to the next purchaser, so subsequent wholesalers are unable to obtain the pedigrees needed to sell their products;

—The pedigree for a product that circulates several times through the supply chain loses all prior sales history if the drug product is sold to an ADR;

—The net effect is that secondary wholesalers who cannot obtain pedigrees necessary to legally market drugs could be driven out of business; reducing the number of legitimate distributors in the system, decreasing competition and increasing prices;

—Manufacturers do not update their lists of ADRs so it is difficult for a wholesaler to obtain ADR status; and

—Costs of paper pedigrees outweigh the benefits.

A number of other comments, however, supported the use of paper pedigrees for their deterrent value and as a means to verify prior sales through due diligence. Comments noted that even forged pedigree papers provide an additional opportunity to identify counterfeiters and block introduction of counterfeit drugs into the drug supply if wholesalers exercise due diligence by tracing the sales through the pedigree and identifying the place where the forgery occurred. A few comments suggested that FDA should exercise enforcement discretion and not take enforcement action against a wholesaler who fails to provide pedigree information back to the manufacturer as long as the wholesaler provides pedigree information back to the first ADR who received the drug from the manufacturer.

Several comments suggested a risk-based approach to implementation of the PDMA, which focuses on those drugs that are at high-risk of being counterfeited. Many of these comments suggested that high-risk drugs maintain a full pedigree that documents all sales and transactions back to the manufacturer. One comment suggested an interim solution of "one forward, one back" pedigree for high risk drugs. This system would be analogous to recent bioterrorism legislation for food distributors, whereby participants in the food distribution system maintain only those records necessary to identify immediate previous sources and immediate subsequent recipients of food. However, comments on FDA's food regulations have suggested it will take at least several years to phase in the paper recordkeeping requirements. Moreover, in contrast to drugs, there are no major steps in development now to provide widespread electronic pedigrees for drug products. Finally, as noted throughout the riskiest drug products are the ones for which modern anti-counterfeiting and track-and-trace methods should be implemented soonest.

Most comments supported the development of an electronic pedigree for all drug products in the supply chain and that an electronic pedigree should be considered

as a long-term solution to fulfilling the PDMA requirements codified at 21 CFR 203.50. Given the costs of implementing the partial anti-counterfeiting measures included in the PDMA, and the expectation of continued significant progress toward implementation of modern pedigree systems for drugs, more effective modern pedigree systems are likely to be available before it would be possible to phase in and achieve compliance with paper pedigree requirements.

Model Rules for Wholesale Distributor Licensing

The comments overwhelmingly supported strengthening requirements governing the licensure and oversight of wholesale distributors. Many comments cited the systemic weaknesses in the oversight of the wholesale drug industry, prior to Florida's implementation of licensing reform, that were described in the Florida Grand Jury Report, such as issuing licenses without proper background checks and granting licenses despite one or more felony convictions. The comments also stated that existing inspection and due diligence processes are often insufficient to detect criminal activity. As mentioned above, there was uniform agreement that the penalties for counterfeiting drugs are insufficient to serve as an adequate deterrent.

Many comments supported the concept of tighter requirements generally, while others gave specific suggestions for improvement. Some of the specific suggestions included:

—Detailed and robust applications that provide greater disclosure of information about the applicant and their prior history;
—Criminal background checks for applicant and company principals;
—List of prescription drug-related or fraud-related activities that are "not in the public interest" such that states should deny licenses to persons with criminal records for these activities;
—Pre-license inspection of wholesale distribution facilities;
—Periodic and unannounced inspections;
—National clearinghouse for information on wholesale licensure status, debarments, exclusions, and/or results of criminal background checks;
—Bonds of up to $100,000;
—Requiring all wholesalers to transmit pedigree tracing transactions back to the manufacturer for susceptible products;
—Non-ADRs must pass pedigree with all drugs with transaction information back to an authorized distributor;
—Amending the definition of ADR to include those on the manufacturers list, have a written agreement currently in effect with the manufacturer, or has a verifiable account with the manufacturer and minimal transactional or volume requirement thresholds from the manufacturer of 5,000 sales units within 12 months or 12 purchases (invoices) within 12 months;
—Requiring authentication of pedigree if there is reason to suspect that the product may be counterfeit, as well as on a random basis;
—Migrating to electronic pedigree;
—More aggressive penalties and enforcement on state and national level;
—Quickly suspending and/or revoking licenses of violators; and
—Including due diligence requirements for wholesalers to conduct on its suppliers.

Most comments stated that the stricter standards should be uniform across all 50 states so as not to create 50 different sets of criteria and rules for licensing.

Concerns about several provisions in the new Florida and Nevada laws regarding licensing of wholesale distributors were expressed. Some of the comments described implementation and logistical problems that wholesalers have experienced in these states as a result of the new law.

Some comments encouraged FDA to revsit the minimum standards requirements described in 21 CFR Part 205 to create a "Federal floor" for States to meet. The comments were not uniform, however, on whether such a Federal floor might enhance or deter state efforts to implement the complete set of NABP recommendations.

Counterfeit Alert Network for Information Dissemination and Education

The agency received many supportive comments about the counterfeit alert network concept. Most of the comments suggested that the agency use existing networks and several comments offered their organizations distribution list or network as a conduit for the counterfeit alert network.

Some comments offered strategic approaches for the development of such a network, including suggested concepts for message delivery. Suggestions include using active notification via "push" e-mail technology, validated and secure systems, easily understood language with clear and unambiguous messages, multiple notification systems, accessible to all stakeholders, no cost for users, timely, visual alert to flag

importance, redundant delivery vehicles such as email, fax, direct mail, and phone, and have an embedded link to take user back to FDA or MedWatch website. The comments also suggested that consistency is an important element so there is familiarity in times of emergency situations. The agency was warned not to overuse the counterfeit alert network in order to avoid alert "fatigue," which could create indifference or doubt regarding the importance of the messages.

The agency was encouraged to consider public/private partnerships to design communication strategies and facilitate efforts to standardize anti-counterfeit communications and to augment and coordinate communication systems. The comments also said that costs to FDA and private partners should be kept to a minimum.

Senator BENNETT. Thank you. I appreciate the opportunity to ask questions of all four of you, and, again, thank you for your service.

Senator Kohl.

WIC CONTINGENCY FUND

Senator KOHL. Thank you, Mr. Chairman.

Mr. Bost, last week, when Secretary Veneman was here, I noted that States are already starting to take action to conserve WIC dollars because they are afraid they do not have enough money to finish out this year. I said we have a contingency fund to prevent things like this from happening and States need to be given as much advance notice as possible if contingency fund money will be made available.

At that time the Secretary said that USDA was aware of the problem and was looking into it. It has been a week now and we have not heard anything, so I would like to ask you the question that we asked her: Do you anticipate using any of the contingency fund this year? And when will an announcement be made with respect to this issue?

Mr. BOST. Well, Senator Kohl, it is interesting that you ask the question because the money was released to several States last night.

Senator KOHL. Last night.

Mr. BOST. Last night.

Senator KOHL. That is great. You know, I cannot imagine——

Senator BENNETT. He knew you were going to ask the question.

Senator KOHL. You cannot respond any more quickly than that.

Mr. BOST. Beg your pardon?

Senator KOHL. That is terrific.

Mr. BOST. Well, I think to be perfectly——

Senator KOHL. So the contingency funding is being made available.

Mr. BOST. Well, actually the States should have it in their letter of credit as we speak. They probably received it at midnight last night.

Senator Kohl, I think it is really important to note, too, that the issue of tracking that information from the States in terms of looking at participation and looking at the food cost is it is not an exact science. And we have been following it for some time. And we were trying to look at being as judicious as we possibly could with those contingency funds, but we did release them last night to those States that were in need, and they will not have to stop serving any clients that are eligible.

WIC FOOD COSTS

Senator KOHL. A follow-up on that. Can you confirm that WIC food costs have been higher than anticipated and that the food cost assumptions upon which the fiscal year 2005 funding request was based are now outdated?

Mr. BOST. Well, I don't know if I would say that they were outdated, but I think the preliminary information that we currently have available to us and that we have been reviewing would lead us to believe that the overall food costs are a little bit higher than estimated.

The other point I would like to make is that it is not only an issue of food cost, but it is also participation rates. In some States, the food costs are a little bit higher; in some States, it is not. We are watching and tracking it very, very closely. It is something that we are very concerned about.

Senator KOHL. And do you anticipate that this updated data and increased participation rate will make it likely that we will have to provide some additional resources in fiscal year 2005 for WIC?

Mr. BOST. I don't think I have drawn those conclusions at this point. It is something we are watching very closely. If we see that is indeed the case, we will come and work with you and Congress to ensure that the needs of these persons are met.

Senator KOHL. Good.

NATIONAL ORGANIC PROGRAM

Mr. Hawks, in fiscal year 2004, we provided a significant increase in funding to the National Organic Program and required that part of the funding be used to meet several statutory requirements of the Organic Foods Production Act of 1990 that have not yet been met. These include directives to hire an executive director for the National Organic Standards Board, to create an ongoing peer review panel, and to improve scientific technical support for the Organic National Standards Board.

Could you comment on the progress of the agency with respect to each of these three funding directives?

Mr. HAWKS. Yes, sir. We are making extremely good progress toward hiring. I think the executive director is very close to being hired. My staff tells me that we are moving judiciously in all of these areas with regard to organic.

Senator KOHL. The peer review panel, do you know if that is ongoing or are you moving in that direction? Have you created an ongoing peer review panel?

Mr. HAWKS. We are in the process of completing initial peer review as we speak.

Senator KOHL. And, finally, to improve scientific technical support for the National Organic Standards Board, any comment?

Mr. HAWKS. Yes, sir. We are doing that. The funds that were provided in our 2004 budget are helping us on the technical scientific review as well.

Senator KOHL. That is great.

Mr. HAWKS. We appreciate those funds.

ANIMAL FEED INSPECTIONS

Senator KOHL. Yes, thank you.

Dr. Crawford, FDA recently announced that they would be implementing new rules regarding animal feed as a result of BSE, including increasing inspections of rendering plants and feed mills. An increase of over $8 million is provided in the budget for this purpose. How many rendering plants and feed mills are in the United States? Of those, how many handle ruminant material prohibited from being used in animal feed? And will these inspections, specifically of plants that handle ruminant material be physical inspections or paper audits? And what about plants that do not handle ruminant material?

Dr. CRAWFORD. With respect to the number of plants and what they handle, if it is agreeable, I would like to submit that for the record.

The second thing is the inspections will be doubled next year. We are asking for that in this budget. The kinds of inspections will be both physical and also audit types. We expect for the plants to know where the material came from and where it is going, and we have records access for that. And we will be evaluating that.

The other thing is that we want to know what kinds of materials went in there and what the feed was used for and whether or not we can trace that in order to be sure that it isn't going to the wrong species.

So it is a fairly complex inspection process that is reflected in that $8.3 million more that we want for BSE. One of the major things we are trying to do is to control BSE because the most likely source of infection is animal feed, as you know.

[The information follows:]

ANIMAL FEED

As of February 6, 2004, there are 235 rendering plants, 1,085 FDA licensed feed mills, and 5,071 non-FDA licensed feed mills in the United States. Of these, 157 rendering plants, 310 FDA licensed feed mills, and 759 non-FDA licenses feed mills handle materials prohibited from being used in animal feed.

Senator KOHL. All right. Dr. Murano, your budget requests an additional $23,500,000 for the Food and Agriculture Defense Initiative. Funding is also requested in FDA and other agencies for this. It sounds like the increases are going for computer system upgrades, increased surveillance, bio-surveillance and training.

For those of us who are not steeped in the language of homeland security, can you explain in laymen's terms what this money will be used for?

Dr. MURANO. Certainly. As you said very well, this is a coordinated effort between ourselves and FDA and other agencies as well, because we understand that we must do several things to maintain the safety of our food supply from intentional attack. One is surveillance, so both we and FDA need funds to survey the food supply for specific agents that we do not normally test for, for what we deem to be normal contamination of food. These are threat agents for which both of these agencies have conducted vulnerability assessments to see where we are the most vulnerable. We have determined where we are the most vulnerable, and are trying

to close those gaps and then test for the threat agents that we believe are most likely to be used.

Secondly, the Food Emergency Response Network that I described very briefly in my opening remarks, is also a joint effort with FDA. It is a network of laboratories throughout the entire country that have to work together and be well coordinated to respond to an event. More importantly, it must do the important surveillance work that needs to be done even before an event takes place. All of these labs have to be coordinated in terms of using the same methods and the information has to be shared among all the laboratories. That is why part of the funds are being asked for eLEXNET, which is a web-based information sharing platform.

For all of these reasons, we have our budget request and FDA has their budget request, but funds are to be used jointly to establish a very robust network of 100 labs in this coming year.

WIC-ONLY STORES

Senator KOHL. All right. Mr. Bost, I have recently been informed about a growing problem that is costing the WIC program several million dollars a year. The WIC-only stores that, as you know, serve only WIC clients and accept only WIC certificates, are increasing in numbers very rapidly. In California alone, there were 82 WIC-only stores in 1996, and now there are more than 600 across that State.

The problem with these stores is that they do not have to compete in the normal market, and so they are able to charge extremely high prices for their products. In California, the estimates are that the WIC-only stores charge 15 percent or more in addition to normal price for WIC food packages than other stores. This is a growing problem, and the WIC program obviously is suffering additional, unnecessary, and unprogrammed costs because of it.

With money so tight, obviously, Mr. Bost, we need to do as much as we can to control this problem. Can you comment on the problem? And to what extent are you aware and consider it serious and what you may be doing about it?

Mr. BOST. Well, interestingly enough, Senator Kohl, I think it is important to note that only 2 percent of all the authorized WIC vendors are essentially WIC-only. Right now we have the WIC-only stores only in California and in the Commonwealth of Puerto Rico. So, one, it is not widespread.

The second point is the fact that we have heard anecdotally that the cost to the Federal Government is more. However, the service is better than our clients are receiving other places. So we are in the process of reviewing that data to make a determination, if it is accurate information, generally speaking, is the cost more. So we have just started that review. I think we actually have two of my senior staff that are going to go into some of the stores in California over the course of the next couple of months and ascertain exactly what the situation is. We are concerned given the fact that we are seeing an increase in our overall WIC costs.

CRITICAL PATH INITIATIVE

Senator KOHL. Yes.

Dr. Crawford, FDA recently announced that they are going to use new technologies to help reduce the cost of developing new drugs. While the goal of this announcement is definitely worthy, announcements such as these raise a question of how closely the FDA should be working with the industry that it regulates.

What considerations are being taken before FDA makes a decision on something that will cause them to work in close collaboration with the industry that you are regulating?

Dr. CRAWFORD. Thank you, Senator Kohl. As you know, we are bound by very strict ethical guidelines to keep us from acting and colluding with the industry that we regulate. We have to be very careful about that.

Our record has been good over the years, but we want to keep it good and even better. So we are separated from working directly with the industry, either in a consulting capacity or in any other kind of capacity to improve their bottom line, their profitability, and even the approval of these drugs.

The genesis of this program, which we are very pleased with, is some years ago, as you know, there was a move to double the National Institutes of Health budget. And so that budget went from between $13 and $14 billion, to $27 billion. This is expected with some concomitant increases in industrial research and development to produce a large number of new technologies and scientific developments that could and I believe will lead to the capability of this country and its pharmaceutical industry producing more useful products, not just in the human drug category but probably in other categories.

The bottleneck for these breakthroughs periodically in terms of getting the technology from the laboratory to the patient and, therefore, saving lives and improving the well-being of people in this country and in other countries has sometimes been the Food and Drug Administration. Obviously, if a large number of new products are developed as a result of the NIH research and the research that is taking place in the pharmaceutical world, we have to be ready for them. We have to know what kinds of categories of products are coming. We have to have the personnel that can rapidly, accurately review these products so that we are sure they are safe and effective, but also to get them to the market as quickly as we possibly can, consistent with their safety and efficacy. That needs a new mind-set, a new model at FDA, and we call it the Critical Path from the laboratory to the patient. It is a modest program to begin with, but it does require us to rethink how we do this.

Now, in saying that, although we will not be divorced from cooperating with NIH, we will be distanced from the pharmaceutical industry that we regulate as we try to get together a new system. So thank you for the question, and I assure you we will be separated to the maximum ethical extent.

BIOTERRORISM REGULATIONS

Senator KOHL. Thank you.

Dr. Crawford, it was recently announced that FDA would delay publishing a final rule on contaminated food tracking by 2 months. The purpose of this rule, as you know, is to help FDA track down

contaminated food and food ingredients as quickly as possible, and it has been lauded by consumer groups.

Why did the FDA postpone publishing the rule? Can you give us a date certain by which the rule will be published?

Dr. CRAWFORD. Thank you for the question. When the Bioterrorism Act was passed in June of 2002, we did get the authority to do this kind of thing, the recordkeeping authority that you are talking about, as well as three other new authorities which enable us to police the food supply better than ever before, thanks to the wisdom of the Congress. This is something that had been developing for a long time, but the advent of the terrorist threats that we are all aware of moved the Congress and also moved the agency to work together to try to get this passed.

We are delayed a bit from what we projected in December with publishing this final regulation. Exactly when it will come out we are not sure at this point. It shouldn't be very much longer. We are putting the finishing touches on it, and we are working with the administration to get it forward.

But I wanted you to know and I wanted to say for the record that the authority to take these kinds of action exists. We just have not implemented the regulations which set out how we will do it. But we are acting already and we are protecting the food supply through the authorities that were vested in us by the Bioterrorism Act.

BSE

Senator KOHL. Finally, Mr. Hawks, the Secretary announced on March 15th that USDA would greatly enhance BSE testing over a year to a year and a half period, 12 to 18 months. Do we understand that this enhanced testing is scheduled only for this limited length of time? And if test results show any additional BSE-positive cases in the United States, will USDA further enhance testing and continue it for an indefinite amount of time? And if so, will CCC funds be used for that purpose, or how will these costs be covered?

Mr. HAWKS. Thank you, Senator Kohl. You are exactly right, we did announce on March the 15th our enhanced surveillance package. We also announced that $70 million would be transferred from CCC to implement this enhanced surveillance plan. This is in keeping with the international review team report, which recommended that we conduct very intensive surveillance of the targeted population for a period of 1 year. So that is what we have to do. Determinations will be made about where we move from here when we see what we find with this surveillance plan.

Our objective is to try to get as many of these samples as we possibly can. If we collect approximately 268,000, we believe this sampling will show one BSE positive animal in 10 million adult cattle a 99-percent confidence level. We are very committed to this. We are also testing a random sampling of normal animals in this process. We are working with the industry to make sure that we are able to get these samples as well.

So I think the answer is we will have to see where we are, see what the surveillance turns up, and then it would be appropriate to make determinations about how to proceed after that.

Senator KOHL. What happens in the public eye, Mr. Hawks? We tested one animal for BSE, and there was a panic across our country. Suppose you find one other animal or two other animals out of—how many do you intend to test?

Mr. HAWKS. We are going to test as many of the target population as we possibly can. We have been testing roughly 20,000 per year for the last 2 years. This year, we had intended to test 40,000. Now our goal is to test as many as we possibly can for the next 12 to 18 months.

Senator KOHL. Well, suppose you test 5 million and you find five and you announce that. I suppose you would announce that, right?

Mr. HAWKS. Well, I think statistically speaking, if we test 268,000 from the target population, it is almost as good as testing——

Senator KOHL. All right. Suppose you do and you find three more or four more.

Mr. HAWKS. The measures that we have already taken to protect food safety, including the removal of specified risk materials, those measures have been taken to ensure that the food supply is safe. And I think whether we find one more, or whether we find three more, or if we don't find any more, the measures that are in place are there to adequately protect our public.

The U.S. case is totally unlike what happened in Asia. In Japan, there was a total loss of consumer confidence. As we have seen in this country and in Canada as well, our consumers believe that we are doing a good job in protecting food safety. I will eat beef quite often. So I think it is very important to understand that I have total confidence, Dr. Murano has total confidence, because that is her responsibility as well. We share those responsibilities.

Senator KOHL. I thank you so much, Mr. Hawks.

Senator Burns.

Senator BURNS [presiding]. Senator Kohl, how are you this afternoon? I noticed that the chairman here asked me to come down here and to really mess up this whole hearing. He sent the right guy. And he has already covered a lot of these things: obesity, as if he had a problem.

Senator BURNS. And I am glad he took care of that before I got here. So let's go down the line.

By the way, first of all, since I have got you here, Mr. Hawks, and most of you, we all know that we probably dodged a humongous bullet last December the 23rd and again May the 4th up in Canada. We didn't have to go through the situation the Canadians went through up there.

I appreciate your actions, and I know it was the cow that stole Christmas, but, nonetheless, it was one of those things. And I don't know what my telephone log looks like, but it was pretty full.

I talked to the Secretary yesterday, and I expressed my gratitude, and I think it was done as well as it could be done for a bureaucracy. So I am happy about that. However, we still come under some criticism, but, nonetheless, it is usually criticism that probably does not quite understand how the system works and what we did.

If we tested 100 percent—I don't know. You might have already been asked this question, and I apologize if you have been. If we

started testing tomorrow 100 percent of our production in the beef market right now, do you think that export market would just snap back overnight?

Mr. HAWKS. No, sir, I do not. We did discuss this earlier. I think 100 percent testing has absolutely no scientific justification. I believe that the path that we are on with the aggressive surveillance, with the measures that we have taken to remove SRMs and the measures that FDA is announcing to put additional firewalls in place are more than adequate to prevent the spread of BSE if it is here and also to protect food safety.

NATIONAL ANIMAL IDENTIFICATION

Senator BURNS. Let me ask you another question. How are you moving on the national ID system?

Mr. HAWKS. We are moving very well. As you know, we have been developing a plan over a period of years. USAIP has been working for over 2 years. They have done a tremendous amount of work. The Secretary asked our Chief Informational Officer, Scott Charbo, as well as Nancy Bryson, and our Chief Economist, Keith Collins to look at this, with each one of them looking from their respective viewpoints, the legal, the technological and the economic.

We have put together a plan drawing heavily upon what USAIP is doing. It is certainly our intent later this year to be able to issue premises identifications, and early next year to do individual identifications. We have a few principles that we are working on, such as being technology neutral. We want to make sure that any system that we put in place does not add burden to our producers, as you and I both know and appreciate those concerns. We protect confidentiality of information. So those are some of the things we are addressing.

Senator BURNS. When can we expect to see that plan?

Mr. HAWKS. You should be able to see that plan real soon. It is going through final review at the Department now, and so we hope to have that plan to you in the very near future.

BSE TESTING

Senator BURNS. Give me an idea of those packing facilities that want 100 percent test in order to maybe get into the international market or see what they could do. We have seen a reluctance from the USDA for that. Can you give me an update on that situation and the position that you have taken?

Mr. HAWKS. Yes, sir. Certainly that is continually under review. We do not believe there is, as I have said, a scientific justification for doing 100 percent testing. We have recently approved some rapid-test test kits for use in our surveillance plan. We will continue to review those requests that are before us now in the Department of Agriculture, but we certainly do not believe there is scientific justification for doing 100 percent testing.

Senator BURNS. Tell me, on the test itself, have you settled on a particular test?

Mr. HAWKS. No, sir. We have recently approved two rapid tests for the surveillance plan. We are continuing to review other tests as we speak and hope to have, in the very near future, additional test kits approved for use.

Senator BURNS. When will we see those?

Mr. HAWKS. I would hope to see those, as I said, in the very near future. I am like you, coming into Government out of the private sector. It is very difficult to nail down those exact dates as we could when you and I are out there on the farm.

DENTICIAN

Senator BURNS. We look at those things. I am not an expert on that and I would have none, but I can tell you that I know some people that do know the difference. I think false positives are always out there, those kinds of situations in that respect. Now, age. You have first come out with a system to mouth the cattle. That has not been the most accurate procedure sometimes. In other words, it all depends on a little bit of heredity and genetic makeup of the animal. Also, whether it calved and where they are raised. And so, Dr. Murano, you want to——

Mr. HAWKS. She is our dentician expert.

Senator BURNS. Are you pretty good on horses?

Dr. MURANO. Sir, I will tell you that we have had to come up with a system that would help us determine the age of these cattle, and you are correct in that the dentician method is not perfect. We all know that. We have instructed our inspectors that what they do first and foremost is look, at the records that come with the animals, and use that as their main gauge of the age of the animal. If those records are complete, that is what we go by because that is the most accurate. When those records are not accurate or not available—and I presume that will be corrected once this animal ID system is all in place—the only other method that we have available to us that we know is the dentician.

However, having said that, the regulations that we published January 12th are still under an open comment period, and we have actively sought the input of the industry, any stakeholders, and anyone who may have information and evidence on what might be a better method than dentician. We are surely open to whatever other suggestions the experts in the field have for us, and we will move to do the best job we can and be as accurate as possible.

NATIONAL ANIMAL IDENTIFICATION

Senator BURNS. With a national ID system and a producer that keeps records—and most do now and especially in performance herds; we are doing it more with range cattle more every day to identify those animals who excel in their production and this type thing, I would say—and if we go to some sort of a digital ear tag, that at least the week the animal was born, it would also be part of that record on that ear tag. That is the only thing that I think the ear tag has an advantage over a hot iron brand, but that is a westerner talking and not the general run of the cattle business.

So I think we have to approach that because I will tell you, being in that business, I sat up there the other day, and just to see if I had any talent left at the auction when they were selling cattle the other day at the auction. I sat up there and I still got the touch, I want you to know, right now.

Mr. HAWKS. Are you looking for a job, Senator?

Senator BURNS. No.

I tell you how it can go. A farmer came in and set down beside me, and there was a little package of calves come in, and they probably weigh, I do not know, pretty close to 6 and pretty green. And he just leaned over and he said, "Conrad, what do you think those things will weigh?" And I said, "Do not ask me. I missed the weight of a chicken by 7 pounds one time."

But I really believe that the national ID system, I think you have a working group out there right now that is headed by Gary Wilson out of Ohio, and I have talked with him—he was in town about a week, week and a half ago—on the national ID system, and also on the age, because I will tell you, that age is critical. It is critical because we know of people that some feed calves, some feed yearlings, and then there is a little thing called a heiferette, and we know about those kind of stock, but it is critical as far as the return to the producer, and also critical to the man who sends them to market for slaughter, and how they are graded and this type of thing. Right now it is a pretty rapid market out there right now, especially on that class of cattle and livestock.

We would like to see what you have proposed. We would like to work with you on that, especially that working group on national ID and on age. I also talked to some people that want to do some work as far as verification of the animal from birth to the grocery store, tests along the way. Because there are some plans and programs in the private sector that are being developed, but they will depend on—they want to work with the Department of Agriculture, because we know when we go into the export market, it is the Department of Agriculture who really carries the message into the international market. So we want to do that if we possibly can.

ADDITIONAL COMMITTEE QUESTIONS

As far as the chickens, I know there are probably some people in this room that think chickens is awfully important. I am not one of them.

Only on Sunday every now and again. But I am really concerned about the cattle business.

I do not have any more questions. Senator, are you all done?

Senator KOHL. Yes.

Senator BURNS. I would just be like any other chairman. The record will be kept open for a couple of weeks. We may have some questions from other committee members that will be directed your way. We would appreciate if you would respond to those questions both to the committee and to the individual member of the committee. We appreciate that very much.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR ROBERT F. BENNETT

DRUG INFORMATION WEB SITE

Question. I noted that the FDA recently launched a web site to allow both consumers and the medical community to find comprehensive information about FDA-approved drugs quickly and easily. Since the web site was launched on March 3, how many "visitors" has it had?

Answer. Drugs@FDA has had 154,065 visitors for the period March 3 through April 12, 2004.

Question. Has the FDA received any feed-back from consumers and health care professionals about the ease of access, and whether the information is comprehensive and useful?

Answer. Since March 1, 2004 we have received 70 comments on Drugs@FDA, version 1. It's important to note that there were two previous beta versions of Drugs@FDA on the Internet: beta 1 in June 2003, and beta 2 from September 2003-March 2004. We received a significant volume of very helpful feedback which was incorporated into Drugs@FDA, version 1.

The nature of the comments Drugs@FDA, version 1, ranged from the general (5) we liked it or didn't like it to questions about specific drug products (25) that were referred to CDER's Division of Drug Information for response. Most comments pertinent to Drugs@FDA (40) fall in the category of requesting new features. For example, users requested the ability to search by indication or drug class, wanted more labels added, to obtain NDC numbers and imprint information, to have more regulatory terms added to the glossary, links to the Orange Book, and even the ability to download the database for analysis.

MEDICAL DEVICE REVIEW

Question. According to the 2003 Annual Report of the Office of Device Evaluation, the Center for Devices and Radiological Health was meeting or exceeding most of its MDUFMA-prescribed performance goals in 2002. As previously noted, the fiscal year 2005 budget request includes $25.555 million for this user fee program. What will the FDA actually do with this increased funding?

Answer. The FDA commitment letter defines the performance objectives FDA is pursuing under MDUFMA. It requires FDA to meet challenging objectives for both cycle and decision goals and to pursue a variety of other goals that do not involve quantifiable measures of progress, such as maintaining current performance in areas where specific performance goals are not identified, working with its stakeholders to develop appropriate performance goals for modular review of PMAs, and working to improve the scheduling and timeliness of pre-approval inspections.

The appropriation requested by the President's fiscal year 2005 Budget will provide FDA the resources needed to move forward to effectively implement MDUFMA. Substantial improvement will be required to meet both the fiscal year 2005 performance goals and to lay the foundation for the increasingly challenging performance goals of fiscal year 2006 through fiscal year 2007.

The additional funding will be used to:

—Cover the cost of living increases so that FDA can maintain staffing levels and scientific capabilities to meet the demands of an increasing workload and new challenges;

—Enhance the IT systems that support the current review process and develop system capabilities to facilitate the submission and acceptance of electronic premarket applications;

—Enhance reviewer training and skill maintenance so that FDA reviewers are able to keep pace with rapidly developing and increasingly complex device technologies;

—Employ research and science based activities that provide support critical to the device product approval process;

—Invest in office and laboratory infrastructure to keep pace with rapid technological and scientific change in diverse fields of expertise;

—Work with outside experts to develop guidance and standards to help industry understand and meet FDA requirements, and to help support FDA's role in international harmonization on emerging technologies.

—Expand FDA's small business assistance program as required by the FD&C Act. Approximately 35 percent of the PMAs approved last year were from first time submitters who needed FDA's assistance;

—Conduct pre-approval inspections of device manufacturers;

—Enhance policy guidance document development, emergency response, review management and risk communication for products developed and used to respond to terrorist threats and national security crisis; and

—Contract with professional societies and agencies to address the agency's needs, including the need for adequate laboratory facilities, to plan bio-effects research, and to develop requirements for the safe use of devices.

Question. Since the agency has already reached most of its MDUFMA performance goals, should the FDA be working toward more aggressive goals?

Answer. Although FDA is making satisfactory progress towards achieving the ambitious performance goals established under MDUFMA, the fiscal year 2003 Office of Device Evaluation/Office of In Vitro Diagnostic Device Evaluation and Safety

(ODE/OIVD) Annual Report does not claim or imply that we "have already reached most" of MDUFMA's performance goals. MDUFMA's goals are based on receipt cohorts; for example, the fiscal year 2003 receipt cohort includes applications received from October 1, 2002 through September 30, 2003. For PMAs and PMA supplements, the receipt cohort performance data shown for fiscal year 2003 in the ODE/OIVD Annual Report represents only receipts through March 31, 2003 (6 months of data); for 510(k)s, the receipt cohort performance data shown for fiscal year 2003 represents only receipts through June 30, 2003 (9 months of data). See the footnotes on pages 48, 53, 56, and 68 of the fiscal year 2003 report. Furthermore, the results applicable to our MDUFMA performance goals will change over time as FDA completes work on pending applications. As of March 31, 2004, the following fiscal year 2003 applications were still pending (the numbers were substantially higher when the fiscal year 2003 report was prepared):

—PMAs—21
—Expedited PMAs—1
—180-day PMA Supplements—2
—510(k)s—316

Also, the goals become more stringent beginning in fiscal year 2005.

The ODE/OIVD Annual Report shows promising progress towards achieving MDUFMA's objectives, but those results represent only preliminary indicators of performance. FDA will provide quarterly reports updating our progress towards achieving MDUFMA's performance goals on our MDUFMA web site (www.fda.gov/cdrh/mdufma).

MEDICAL DEVICE/DRUG MARKETING

Question. We have all heard that a particular DC laser surgeon fixed Tiger Woods' eyesight, and that former Senator Bob Dole has benefited from a particular prescription drug. Now we learn that golfer Jack Nicklaus has a new hip made by a particular company. The implications here are if it is good enough for Tiger/Bob/Jack, its good enough for me. What role does the FDA play in monitoring these types of advertisements?

Answer. FDA regulates drugs and medical devices in the United States under the authority of the Federal Food, Drug, and Cosmetic Act (FDCA). This authority extends to promotional labeling for all drugs and devices and advertising for prescription drugs and so-called "restricted" devices. (21 U.S.C. 342(a); 352(a), (n), (q), (r); 362(a).) The Federal Trade Commission (FTC) also has legal authority to regulate advertising (15 U.S.C. 52), and takes the lead in regulating the advertising of OTC drugs and non-restricted devices. FDA takes the lead in regulating the labeling of over-the-counter (OTC) and prescription drugs and non-restricted and restricted devices, and the advertising of prescription drugs and restricted devices.

Advertisements for prescription drugs must include, among other things, "information in brief summary relating to side effects, contraindications, and effectiveness," as specified in FDA regulations. (21 U.S.C. 352(n); see also 21 CFR 202.1.) Advertisements for restricted devices must include "a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications. . . ." (21 U.S.C. 352(r).) Both prescription drug and restricted device advertisements also must not be false or misleading, meaning they must disclose material risk information. (21 U.S.C. 352(q)(1) & 321(n); 21 CFR 202.1(e)(5).) FDA's rules for prescription drug and restricted device advertising are the same, whether the advertising is aimed at a consumer audience or at health care professionals.

The FDCA contains no special rules for celebrity endorsements in advertising. In general, an endorsement could be subject to the general rules for advertising set forth above. Thus, if a celebrity spokesperson were to make a statement in an advertisement for a prescription drug or restricted device that is false or misleading, or if an advertisement contained a celebrity testimonial but lacked the risk information required under the above provisions, FDA likely would have authority to initiate enforcement action under the FDCA. Statements by independent individuals not speaking on behalf of a drug firm are not subject to FDA's advertising jurisdiction. Oral representations by paid representatives of drug firms concerning the safety or effectiveness of a product might also within FDA's regulatory authority if they create a new intended use for a product, for which adequate directions would be required in labeling and for which premarket approval might be required. (See 21 U.S.C. 352(f)(1), 355.)

FDA believes consumer-directed advertisements play an important role in advancing the public health by encouraging consumers to seek treatment. Since 1997, consumer-directed advertisements have been aired (on television or radio) for about 98 prescription drugs. Of those, 14 are intended for under-treated conditions, such as

high cholesterol, heart disease, and mental health problems like depression. Others are for serious conditions such as asthma, Alzheimer's disease, arthritis, chronic obstructive pulmonary disease, diabetes, insomnia, migraine, obesity, osteoporosis, overactive bladder, serious heartburn, smoking cessation, and sexually transmitted diseases.

FDA held a public meeting to discuss the results of FDA surveys and other research on consumer-directed advertising on September 22–23, 2003. Based in part on discussion at that meeting, FDA has developed guidance to encourage advertising that provides risk and benefit information appropriate to support conversations between consumers and their health care providers. On February 4, 2004, the agency issued three draft guidance documents, addressing (1) options for presenting risk information in consumer-directed print advertisements for prescription drugs, to encourage use of consumer-friendly language and formats (2) criteria FDA uses to distinguish between disease awareness communications and promotional materials, to encourage manufacturers to disseminate disease educational messages to the public, and (3) a manner in which restricted device firms can comply with the rules for disclosure of risk information in consumer-directed broadcast advertising for their products, to help encourage compliance in this emerging area of medical product promotion.

FDA has adopted a comprehensive, multi-faceted, and risk-based strategy for regulating consumer-directed advertising of medical products. This strategy includes legally sustainable letters, guidance development, frequent informal communications with industry and advertisers, and research on the public health effects of consumer-directed promotional materials. We continue to monitor the impact of consumer-directed promotion on the public health.

METHYLMERCURY ADVISORY FOR SEAFOOD

Question. As you will recall, Dr. Crawford, in the Statement of the Managers to accompany the fiscal year 2004 Omnibus Appropriations bill, the conferees encouraged coordination between the FDA and the EPA on what is considered a safe level of methylmercury exposure. I was pleased to note that an updated consumer advisory regarding fish consumption and methylmercury was released in mid-March. How does this new advisory differ from that which was released by the FDA in July of 2002?

Answer. The FDA issued an advisory for mercury in fish in March of 2001; this advisory was then reviewed by the FDA's Food Advisory Committee (FAC) in July 2002. There was no new advisory issued in July 2002. The FAC made six recommendations at their meeting in July 2002 as follows:

—Better define what is meant by "eat a variety of fish" so that consumers can follow this recommendation effectively;
—Work with other Federal and State agencies to bring commercial and recreational fish under the same umbrella;
—Publish a quantitative exposure assessment used to develop the advisory recommendations;
—Develop specific recommendations for canned tuna, based on a detailed analysis of what contribution canned tuna makes to overall methylmercury levels in women;
—Address children more comprehensively in the advisory to relate dietary recommendations in the advisory to the age/size of the child; and,
—Increase monitoring of methylmercury to include levels in fish and the use of human biomarkers.

Based on these recommendations, meetings with stakeholders, focus group testing as well as further input from the FACs in December 2003, the FDA issued a revised advisory on March 19th 2004. The revised advisory differed from the 2001 advisory in a number of ways as follows:

—The 2004 Advisory is a joint advisory by FDA and EPA that addresses both commercial caught and locally caught fish and shellfish;
—The 2004 Advisory more strongly emphasizes the positive benefits of eating fish;
—The 2004 Advisory provides examples of commonly eaten fish that are low in mercury;
—The 2004 Advisory and the Question and Answers section specifically addresses canned light tuna and canned albacore ("white") tuna, as well as tuna steaks;
—The 2004 Advisory recommends not eating any other fish in the same week as locally caught fish are consumed (the Advice on the amount of locally caught fish to eat is the same as in the 2001 EPA advisory); and,
—The 2004 Advisory contains a section that addresses the frequently asked questions about mercury in fish.

The 2004 advisory was revised to provide useful information for keeping fish as part of a healthy diet and at the same time reduce the exposure to mercury. The 2004 Revised Advisory more accurately reflects the purpose of the information.

NEW DRUG APPROVAL PROCESS

Question. The FDA recently issued a report which described the decrease in the number of new innovative drug application, and recommends reform to the existing regulatory process. I would appreciate it if you could explain just exactly what the FDA plans to do in this regard.

Answer. The "critical path" is best described as the crucial steps that determine whether and how quickly a medical discovery becomes a reliable medical treatment for patients. There are certain points on this path where difficulties are occurring. FDA believes that a major problem in today's drug development process is that the new science and scientific tools being used in the discovery process are not being harnessed to guide the development process that brings products to market. FDA has called for a new focus on modernizing the tools that applied biomedical researchers and product developers use to assess the safety and effectiveness of potential new products, and the manufacturing tools necessary for high-quality mass production of cutting-edge therapies. FDA is in a unique position to identify scientific challenges that cause delays and failures in product testing and manufacturing because of its experience overseeing medical product development, assessment, and manufacturing/marketing; its vast clinical and animal databases; and its close interactions with all the major players in the critical path process.

FDA, through collaboration with academia, patient groups, industry, and other government agencies, will play a major role in identifying systemic medical product development problems via development of a Critical Path Opportunities List, and in conducting or collaborating on research to create a new generation of performance standards and predictive tools that will provide better answers about the safety and effectiveness of investigational products, faster, with more certainty, and at lower costs. Specific examples of critical path efforts include: developing guidances and scientific workshops on "best practices", developing new animal or computer-based predictive models, developing new biochemical and genomic assays as biomarkers for safety and effectiveness, collaboration on the design of new clinical evaluation techniques, and facilitating multi-company studies of technologies which no one company could mount. FDA will identify and prioritize the most pressing product development problems and the areas that provide the greatest opportunities for rapid improvement and public health benefits across the three dimensions of the "critical path"—safety assessment, evaluation of medical utility, and product industrialization and will facilitate collaborative research in these areas.

Question. A consumer group has expressed the opinion that the FDA should approve only drugs which show concrete advantages to drugs currently on the market. What is your response to that suggestion?

Answer. Our present and future mission remains constant: to ensure that drug products available to the public are safe and effective. If the drug is effective and we are convinced its health benefits outweigh its risks, we approve it for sale. Statutory requirements dictate that we review products submitted to us requesting approval. From a medical perspective, it is desirable for physicians and consumers to have a variety of drug treatment choices. Not all people can tolerate a specific drug. Not all drugs have the intended affect in every person. From an economic perspective, it is also useful to have a market featuring a variety of products so that prices are competitive.

SEAFOOD INSPECTION/GAO REPORT

Question. The General Accounting Office recently issued a report on the FDA's imported seafood safety program. Basically, GAO found that although the FDA has made some progress in the number of foreign firms being inspected and the number of seafood products being tested at U.S. ports of entry, there is more work to be done. Among other things, GAO recommends that the FDA work with NOAA to have NOAA employees provide various services under their Seafood Inspection Program. Have you reviewed this GAO report? Do you agree with their observations? What steps has the FDA taken to work with NOAA in this regard?

Answer. FDA reviewed the GAO report and provided a lengthy comment to the GAO on this particular recommendation. The comment was published in the Appendices to the report. In summary, FDA noted that it has a long and collegial working relationship with the seafood inspection program within the National Marine Fisheries Service (NMFS) and that the two agencies will be working together to find better ways of integrating their programs. Potential areas of integration were de-

scribed, including the use of NOAA laboratory capacity to carry out analyses of seafood samples that FDA takes during the normal course of work; the commissioning of NMFS inspectors; the use of NMFS inspectors who might already be on site in distant locations; and the issuance by NMFS of European Health Certificates for a fee to U.S. industry that ships fish and fishery products to Europe. The latter would free up FDA resources that are now devoted to that activity.

We have recently worked with NOAA Fisheries' National Seafood Inspection Laboratory (NSIL) located in Pascagoula, MS and the NOAA Fisheries' Northwest Fisheries Science Center in Seattle, WA to assess the use of NOAA laboratory capacity to carry out analyses of seafood samples that FDA takes during the normal course of our work, or during "crisis" situations. Specifically for chloramphenicol analysis, our discussions have resulted in FDA's provisional approval (pending on site review) of these laboratory's methods for sample submission, custody, routing, and accounting and documentation procedures necessary to maintain the regulatory chain of custody and tracking required for import collections. While FDA is not able to fund this initiative this fiscal year, we hope that we will be able to implement this proposal in the future.

AGRICULTURAL PRODUCTS

Question. The White House Office of Science and Technology Policy, (OSTP) had recommended approximately 2 years ago (August 2, 2002) that various agencies—including the FDA—complete guidelines regarding the early safety assessment of agricultural products developed through biotechnology for food and feed use. To date, there is no evidence that the FDA has acknowledged this mandate nor made any progress towards finalizing a policy. The U.S. regulatory system currently imposes a zero tolerance on the presence of unapproved biotech-enhanced events in food and feed, regardless of the risk level. It does not recognize the realities of a biological system. This zero-tolerance' policy exposes grain handlers, food processors and feed manufacturers to the risk that any trace amounts of biotech-enhanced events in general commodity crops that have not been approved for food and feed under the U.S. regulatory process could render such crops adulterated and subject to seizure under Federal law. Such a policy is inconsistent with other food purity standards which have established thresholds for trace amounts of unexpected materials. Without having a policy in place, the United States risks significant disruptions in global agricultural trade. What is the FDA doing to meet their obligations and will they be able to complete their work by year's end?

Answer. On August 2, 2002, OSTP announced proposed Federal actions to update field tests requirements for biotechnology derived plants and to establish early food safety assessments for new proteins produced by such plants. As part of this proposal, FDA announced that it would publish for comment draft guidance to address the possible intermittent, low level presence in food and feed of new non-pesticidal proteins from biotechnology-derived crops under development for food or feed use, but that have not gone through FDA's pre-market consultation process. FDA is preparing draft guidance and expects to publish the draft guidance for comment this year.

TRANSGENIC ANIMALS IN CVM

Question. The FDA has resources in place for regulation of transgenic animals in CVM. However, the agency has to date not provided any guidance to industry for the regulation of transgenic animals. What is the FDA doing to refine and clarify the regulatory process for transgenic animals, and when can we expect to see specific regulatory guidance published?

Answer. It is true that CVM has not issued any general guidance to industry for the regulation of transgenic animals. Instead, CVM has worked with investigators one-on-one to ensure safe and efficient development of animal biotechnology products while an interagency group led by the White House Office of Science and Technology Policy (OSTP) develops a coordinated framework that is appropriate to animal biotechnology.

In 1984, the Federal Government embarked on project to develop a Coordinated Framework for regulation of biotechnology products. The early efforts focused on plant biotechnology for agricultural purposes. The effort has resumed at various times as new categories of products became feasible. For example, in May 2000, the White House directed its Council on Environmental Quality, "CEQ", and Office of Science and Technology Policy to conduct an interagency assessment of Federal environmental regulations pertaining to agricultural which includes both plants and animals, biotechnology and, if appropriate, make recommendations to improve them.

Information is available on the internet at http://www.ostp.gov/html/ceq_ostp_study1.pdf.

The White House-directed interagency process continues with respect to animal biotechnology products. The OSTP has convened over the last year an interagency group—which was similar to the group convened in May 2000—with FDA, APHIS, EPA, and OMB, represented. The group is focusing on the application of the Coordinated Framework to the wide range of animal biotechnology products that have been developed since the framework was created in the 1980's. There were very few examples of animal biotechnology products available to consider in the 1980's and only a limited number in 2000. The discussions are continuing, using various product examples, and including listening sessions with various stakeholders. Ultimately, a seamless Federal oversight system for animal biotechnology products is expected.

Both as part of this interagency process and separately, FDA has examined—and continues actively to consider—the many complex legal, scientific, and policy issues related to animal biotechnology. FDA has a variety of authorities potentially applicable to transgenic animals, including FDCA authorities over foods, food additives, and new animal drugs. In 2000, FDA commissioned the National Academy of Sciences/National Research Council Committee on Agricultural Biotechnology, Health, and Environment, (NAS) to identify and rank, where possible, potential risks associated with the introduction of animal biotechnology into commerce. FDA is using the resulting report recommendations, issued in the fall of 2002, as guidance in developing an action plan for the future. FDA is also preparing a risk assessment on animal clones and considering risk management measures that might be appropriate as a condition for marketing animal clones for use in the human food chain.

FDA is also involved in considering issues relating to particular applications of animal biotechnology. In March 2003, FDA began investigating and contacting universities engaged in genetic engineering research to ensure that genetically engineered animals do not enter the food or animal feed—as rendered animals—supply. In May, FDA issued a letter to the Presidents of the Land Grant Universities and posted the letter for more general access on its website. Information on the "Letter from FDA to Land Grant University", from May 13, 2003, may be found on the internet at http://www.fda.gov/cvm/biotechnology/LandGrantLtr.htm. Roughly 2 dozen organizations have responded to FDA's outreach and identified multiple projects with transgenic animals. FDA is monitoring these and other projects as appropriate.

FOOD SAFETY

Question. The Chicago Tribune recently published an article regarding the rising threat to the U.S. food supply. Many of the quoted experts used the word "scary" in describing our vulnerability. What strategy, if any, has the FDA adopted to counter intentional tampering with the U.S. food supply. An additional $65 million was requested in the fiscal year 2005 budget request for food defense. What exactly does the FDA plan to do with these funds? What outputs will these funds provide?

Answer. FDA employs five food defense strategies:

—Development of increased food security awareness among Federal, State, local, and tribal governments and the private sector by collecting, analyzing, and disseminating information and knowledge (awareness);

—Development of capacity for identification of a specific threat or attack on the food supply (prevention);

—Developing effective protection strategies to "shield" the food supply from terrorist threats (preparedness);

—Developing a rapid, coordinated response capability to a terrorist attack (response); and,

—Development of capacity for a rapid, coordinated recovery from a terrorist attack (recovery).

FDA's plan to protect the food supply will be executed on both the import and domestic fronts.

The fiscal year 2005 requested increase of $65,000,000 for Counterterrorism food defense includes $35,000,000 (including eLEXNET) to establish the Food Emergency Response Network (FERN) for increasing lab testing capacity in the event of a threat to the food supply. Roughly $23,000,000 of FERN funds will be available to States for establishing food lab emergency response capabilities and $5,500,000 for infrastructure costs. The request also includes $15,000,000 to address a significant research need for ensuring that we have the capability of detecting or inactivating a broad range of agents that could pose serious threats to the food supply;

$7,000,000 to increase import and domestic inspections activities; $5,000,000 to coordinate with and establish connectivity of our existing food surveillance efforts to the Department of Homeland Security as part of the Administration's bio-surveillance initiative; and $3,000,000 for the Emergency Operations Network project to upgrade our crisis/incident management capabilities in the event of a potential threat to the food supply.

Funds requested for FERN would establish 15 State food emergency response labs, and will also provide an additional 25 labs connected to the eLEXNET, plus necessary infrastructure such as a national operations center to support participating labs. Research funds would ensure that we have the capability of detecting or inactivating a broad range of agents that could pose serious threats to the food supply. The funds for inspections would result in an additional 37,000 import field exams over the projected 60,000 projected level in fiscal year 2004 for a total of 97,000 import field exams. It would also allow for increased surveillance of our food supply by funding an additional 750 domestic establishment inspections. Funds would also upgrade our Emergency Operations Center by investing in the Emergency Operations Network, and would increase coordination of our food surveillance efforts with the Department of Homeland Security.

Question. Last year, the FDA joined with the U.S. Bureau of Customs and Border Protection to develop a program to protect the American public from food bioterrorist attacks. There were high hopes that as many as 420,000 manufacturing, processing, packing, and holding facilities, both in the United States and abroad, would quickly register under this program and provide advance notice of imports in order to expedite the entry process. According to press reports, only about half of those facilities have registered, and food shipments are still arriving without prior notice. Why haven't all covered facilities complied with these requirements? What efforts have the FDA and the Customs Bureau undertaken to make sure that covered facilities register? It is estimated that 25,000 shipments of imported food arrive at U.S. ports of entry every day. Does the FDA have sufficient resources to adequately inspect these shipments?

Answer. In the Registration Interim Final Rule (IFR), FDA estimated that about 420,000 facilities would be covered by the requirements of the rule. In the Prior Notice IFR, FDA estimated that it would handle 25,000 prior notice submissions per day. To clarify the above question, FDA has not estimated that the approximately 420,000 facilities estimated in the Registration IFR would necessarily provide prior notice to FDA.

FDA is unsure why it has only received approximately 200,000 of the expected registrations to date. Because registration is a completely new requirement and covers so many food facilities, FDA believes many small facilities may still be unaware of the registration requirement. FDA continues to place a high emphasis on notifying as many affected entities as possible of the registration requirements through outreach. On April 1, 2004, FDA completed nine city domestic outreach meetings for small businesses and other stakeholders on the registration and prior notice IFRs. FDA's international component of Phase II outreach has been conducted through the collaboration and cooperation of the Department of State through a foreign press conference, Voice of America video teleconference, and USDA's Foreign Agricultural Service. Worldwide attachés disseminated the Registration and Prior Notice interim final rules, compliance policy guidance, and Questions and Answers. FDA, with Customs and Border Protection participation, is also conducting a series of four outreach meetings in Asia from April 21–29, 2004. FDA will continue to conduct outreach in order to notify affected entities of the registration requirement.

In response to the question regarding whether FDA has sufficient resources to adequately inspect the estimated 25,000 daily shipments of imported food arriving at U.S. ports, FDA would like to clarify that the goal is not to physically inspect each shipment associated with a prior notice submission. However, it is important to note that these shipments are reviewed electronically to determine if the shipment meets identified criteria for physical examination or sampling and analysis or warrants other reviews by FDA personnel. This electronic screening allows FDA to concentrate its limited inspection resources on high-risk shipments while allowing low-risk shipments to proceed into commerce.

Prior to receiving our prior notice authority, FDA already was receiving much of the entry information contained in the prior notice submission. However, FDA was not receiving the entry information in advance of the shipment arriving in the United States. With the new prior notice authority, FDA is receiving the entry information in advance of the shipment arriving in the United States (timeframe depends on mode of transportation), and thus, the Agency is better able to focus inspection resources on those shipments for which there is reason to believe they may pose a danger to the food supply.

MONOGRAPH DRUG APPROVAL SYSTEM

Question. The Senate Committee Report to accompany the fiscal year 2004 Agriculture appropriations bill discussed the interest in the establishment of a monograph system for prescription drug products. The FDA was asked to provide a report regarding the feasibility and cost of such a new monograph system for prescription drug products. What is the status of the FDA review of this proposal? If a monograph system is not the appropriate way to go, what efforts has the FDA undertaken to find a way to preserve health and safety while at the same time encourage competition, keep prescription drug prices low, and keep small businesses open?

Answer. In 2003, the Senate Committee on Appropriations asked FDA to prepare a report regarding the feasibility and cost of a new monograph system for prescription drugs that have been marketed to a material extent or for a material time without pre-market approval. The agency is currently preparing that report. The report will analyze critical issues that would need to be addressed if FDA were to develop monographs for the approval of marketed prescription drugs. The report will evaluate the cost and feasibility of developing such a system.

Question. The FDA just extended the comment period for consideration of a guidance document regarding enforcement priorities for older prescription drugs marketed outside of the current new drug approval system. In examining comments, will the FDA examine alternative approaches to the enforcement policy, such as a prescription drug monograph for these older prescription drugs?

Answer. In October 2003, the Agency issued a draft Compliance Policy Guide (CPG) outlining FDA policies to encourage companies to sponsor unapproved drugs through the agency's drug approval process. The draft CPG requests public comment and sets forth the agency's enforcement approach, explaining that FDA will continue to give priority to enforcement actions involving three categories of unapproved drugs: Those that pose safety risks; those that lack evidence of effectiveness; and those that constitute health fraud. It also explains how the agency intends to address those situations in which a firm obtains FDA approval to sell a drug that other firms have long been selling without FDA approval.

FDA received requests to reopen the comment period and has reopened the comment period until April 27, 2004. The Agency will carefully examine all comments, including comments relating to alternative approaches that are submitted on the matter.

PRESCRIPTION DRUG ABUSE

Question. Mr. Crawford, last month the FDA joined with the Office of National Drug Control Policy, the DEA, and the Surgeon General in releasing the President's National Drug Control Strategy. As noted in the ONDCP press release, this marks the first time that any Administration has included the issue of prescription drug abuse in this Strategy. What, exactly, is the FDA's role in this effort? Will the FDA be able to fulfill this mission with existing funds and authorities? If not, were additional resources requested in the fiscal year 2005 budget? Does the FDA need additional statutory authorities?

Answer. The strategy for reducing prescription drug abuse focuses on three core tactics:

First, Business Outreach and Consumer Protection: FDA will work to ensure product labeling that clearly articulates conditions for safe and effective use of controlled substances so that commercial advertising fully discloses safety issues associated with the drug's use. A specific example of this is labeling that properly identifies patients for whom these products are appropriate and that recommend a "stepped care" approach to the treatment of chronic pain, in accordance with treatment guidelines.

FDA will consider Risk Management Programs (RMPs). The Agency will evaluate the need for a RMP during the approval process for Schedule II opiate drug products. RMPs help ensure the safe prescribing and use of these drugs through identification of appropriate patients and monitoring for adverse outcomes.

FDA in conjunction with the DEA and the White House Office of National Drug Control Policy (ONDCP) will work with physician organizations to encourage comprehensive patient assessment prior to prescription of opiate therapy.

FDA and other Federal agencies are enlisting the support of responsible businesses affiliated with online commercial transactions. These legitimate businesses will be asked to alert law enforcement officials to suspicious or inappropriate activities related to these products.

Second, Investigation and Enforcement: The Internet is one of the most popular sources of diverted prescription drugs. An increasing number of rogue pharmacies offer controlled substances and other prescriptions direct to consumers online.

FDA's Office of Criminal Investigation (OCI) and DEA work together on criminal investigations involving the illegal sale, use, and diversion of controlled substances, including illegal sales over the Internet. Both FDA and DEA have utilized the full range of regulatory, administrative, and criminal investigative tools available, as well as engaged in extensive cooperative efforts with local law enforcement groups, to pursue cases involving controlled substances.

FDA and U.S. Customs and Border Protection (CBP), with assistance from DEA, continue to conduct spot examinations of mail and courier shipments for foreign drugs to U.S. consumers to help FDA and CBP target, identify, and stop illegal and potentially unsafe drug from entering the United States from foreign countries via mail and common carriers.

Finally, Protecting Safe and Effective Use of Medications: FDA will support DEA's efforts with medical associations to identify existing best practices in physician training in the field of pain management. DEA and FDA plan to develop a mechanism to support the wider dissemination and completion of approved Continuing Medical Education (CME) courses for use of opioids that include information on the risk of abuse and addiction.

FDA in conjunction with ONDCP and DEA will develop public service announcements that appear automatically during Internet drug searching to alert consumers to the potential danger and illegality of making direct purchases of controlled substances online. Currently, FDA, along with its sister agency, the Substance Abuse and Mental Health Services (SAMHSA), have jointly developed a public service announcement campaign to better educate consumers on the abuse of prescription pain killers.

FDA did not request additional resources in the fiscal year 2005 budget in order to participate in the activities stated above. This initiative does not require additional regulatory authority.

OBESITY

Question. In your prepared remarks you discuss the FDA Obesity Working Group whose recommendations were recently released as part of HHS Secretary Thompson's overarching new national education campaign for combating obesity. What is the FDA role in these anti-obesity efforts? Which of your Centers is responsible for these efforts? What, specifically, is the FDA doing to make sure labels on food is correct, and that claims made about food are factual and science-based? What, if any, additional plans will be implemented in fiscal year 2005?

Answer. In support of the President's Healthier U.S. initiative, the DHHS established a complementary initiative, Steps to a Healthier United States, which emphasizes personal responsibility for the choices Americans make for healthy behaviors. One aspect of this initiative focuses on reducing the major health burden created by obesity and other chronic diseases. Following DHHS' July 2003 Roundtable on Obesity and Nutrition, on August 11, 2003, FDA established an Obesity Working Group, or OWG, to prepare a report that outlines an action plan to cover critical dimensions of the obesity problem from FDA's perspective and authorities. This report was released on March 12, 2004.

There is no simple answer to the problem of obesity. Achieving success in reducing and avoiding obesity will occur only as a result of efforts over time by individuals as well as various sectors of our society. It should be noted, however, that most associations, agencies, and organizations believe that diet and physical activity should be addressed together in the fight against overweight and obesity.

The OWG report provides a range of short and long-term recommendations to address the obesity epidemic with a focus on a "calories count" emphasis for FDA actions. These recommendations are based on sound science and address multiple facets of the obesity problem under FDA's purview, including developing appropriate and effective consumer messages to aid consumers in making wiser dietary choices; establishing educational strategies and partnerships to support appropriate messages and teach people, particularly children, how to lead healthier lives through better nutrition; developing initiatives to improve the labeling of packaged foods with respect to caloric and other nutrition information; encouraging and enlisting restaurants in efforts to combat obesity and provide nutrition information to consumers, including information on calories, at the point-of-sale; developing new therapeutics for the treatment of obesity; designing and conducting effective research in the fight against obesity; and continuing to involve stakeholders in the process.

Regarding food labeling, the OWG report contains several recommendations based on sound science. I will provide these recommendations for the record.

[The information follows:]

Publish an advance notice of proposed rulemaking, or ANPRM, to seek comment on the following:

—How to give more prominence to calories on the food label, for example, increasing the font size for calories, including a column in the Nutrition Facts panel of food labels for percent Daily Value for total calories, and eliminating the listing for calories from fat;

—Whether to authorize health claims on certain foods that meet FDA's definition of "reduced" or "low" calorie. An example of a health claim for a "reduced" or "low" calorie food might be: "Diets low in calories may reduce the risk of obesity, which is associated with type 2 diabetes, heart disease, and certain cancers."

—Whether to require additional columns on the Nutrition Facts panel to list quantitative amounts and percent Daily Value of an entire package on those products and package sizes that can reasonably be consumed at one eating occasion—or declare quantitative amounts and percent Daily Value of the whole package as a single serving if it can reasonably be consumed at a single eating occasion; and,

—Which, if any, reference amounts customarily consumed of food categories appear to have changed the most over the past decade and hence require updating.

File and respond in a timely way to petitions the agency has received that ask FDA to define terms such as "low," "reduced," and "free" carbohydrate; and provide guidance for the use of the term "net" in relation to carbohydrate content of food—these petitions were filed on March 11, 2004. Encourage manufacturers to use dietary guidance statements, an example of which would be, "To manage your weight, balance the calories you eat with your physical activity."

Encourage manufacturers to take advantage of the flexibility in current regulations on serving sizes to label as a single-serving those food packages where the entire contents of the package can reasonably be consumed at a single eating occasion. Encourage manufacturers to use appropriate comparative labeling statements that make it easier for consumers to make healthy substitutions.

We believe that if the report's recommendations are implemented they will make a worthy contribution to confronting our Nation's obesity epidemic and helping consumers' lead healthier lives through better nutrition.

We also believe that the regulatory scheme for claims in food labeling, whether health claims, nutrient content claims, or other types of claims, are science based, and we continue to consider modifications to our regulations to keep up with recent scientific developments. Some of the modifications FDA is currently considering are described above in the list of topics to be covered by the ANPRM the agency intends to issue.

ALBUTEROL METERED-DOSE INHALERS

Question. As noted in the Senate Report last year, there are a number of organizations which support the removal of ozone-destroying CFC albuterol metered-dose inhalers from the market. The FDA has indicated in its regulatory plan that it intends to issue a rule on this matter. Proponents of this rule had expected a proposed rule by now. When can this Committee expect the FDA to issue a proposed rule to remove albuterol metered-dose inhalers from the U.S. market? Can you tell us at this time what you expect the effective date would be for that rule? When do you expect the FDA will issue a final rule?

Answer. FDA is currently working on the CFC albuterol proposed rule and expects it to publish shortly. The rulemaking process prohibits FDA from describing the contents of the proposed rule, so the Agency cannot state the effective date of the rule at this time. FDA expects the final rule to publish in March 2005.

BIOTECH-ENHANCED EVENTS IN FOOD AND FEED

Question. The U.S. regulatory system currently imposes a zero tolerance on the presence of unapproved biotech-enhanced events in food and feed, regardless of the risk level. It does not recognize the realities of a biological system. This zero-tolerance' policy exposes grain handlers, food processors and feed manufacturers to the risk that any trace amounts of biotech-enhanced events in general commodity crops that have not been approved for food and feed under the U.S. regulatory process could render such crops adulterated and subject to seizure under Federal law. Such a policy is inconsistent with other food purity standards which have established thresholds for trace amounts of unexpected materials. Without having a policy in place, the United States risks significant disruptions in global agricultural trade. What is the FDA doing to meet their obligations and will they be able to complete their work by year's end?

Answer. On August 2, 2002, OSTP announced proposed Federal actions to update field tests requirements for biotechnology derived plants and to establish early food safety assessments for new proteins produced by such plants. As part of this proposal, FDA announced that it would publish for comment draft guidance to address the possible intermittent, low level presence in food and feed of new non-pesticidal proteins from biotechnology-derived crops under development for food or feed use, but that have not gone through FDA's pre-market consultation process. FDA is preparing draft guidance and expects to publish the draft guidance for comment this calendar year.

GENERIC BIOLOGICALS

Question. In your testimony you stressed the importance of being "open-minded" about the science "as the science improves." Can you assure the Subcommittee that the Agency will not adopt an approach that resurrects old science, and that the Agency intends to remain open minded as it evaluates application of the vast innovation in analytical tools to the development and evaluation of follow-on biologicals?

Answer. We can assure the subcommittee that the Agency will not adopt an approach that resurrects or relies on outdated scientific techniques in the development and evaluation of follow-on biologics. Indeed, the Agency has been very proactive in striving to understand and embrace the latest technology used in the characterization of biotechnological products. For example, the Agency supports active research programs that utilize current technologies in addressing mission related research and in developing technologies that help address regulatory and scientific issues. These efforts are important to ensure that FDA scientists remain current with the latest advances in analytical techniques. Scientific staff also participates in scientific symposia and extensively interact with colleagues. Indeed, many of our scientific staff involved in the regulation of biotech products, are located on the NIH campus, which provides an enriched research environment utilizing advanced technology that is second to none.

In June 2003, the Agency cosponsored, along with the International Association of Biologicals and the National Institute for Biological Standards and Control, a conference on the "State of the Art Analytical Methods for the Characterization of Biological Products and Assessment of Comparability". This meeting focused on what current analytical technologies can and cannot tell us about the physicochemical structure and function of biological therapeutics;

The Agency's scientists participate yearly in the annual Symposium on "Well Characterized Biotechnological Products" cosponsored by FDA and the California Separation Sciences Society. This symposium includes highly technical seminars, workshops, and poster sessions that introduce the latest analytical technologies for the evaluation of biotechnological products. These technologies are presented by the leading academic, Industrial (pharmaceutical and equipment vendors), and government scientists;

The Agency's scientists actively participate in many International conferences sponsored by biotech and pharmaceutical organizations (Bio, Pharma, and DIA) and other organizations that provide scientific, technological and regulatory information to the pharmaceutical industry. These conferences frequently present the application of the latest analytical methods for the characterization of protein and glycoproten therapeutics;

The Agency also invites innovative scientists from academia and industry to present and discuss with FDA scientists the latest advances in analytical technology and the development of animal models that address some of the current limitations of physicochemical characterization of protein products.

Regarding immune responses to biological therapeutics (immunogenicity), which can cause serious adverse events and limit product effectiveness, the agency cosponsored a meeting entitled "Immunogenicity of Therapeutic Biological Products" in October 2001, and has participated in numerous symposia on this topic in national meetings. Agency research scientists work with industry and academia in bringing to bear, on biological product development, informative animal models (transgenic, knockout, and knock-in) to more accurately predict the human immune response to various biotech products.

Question. In your testimony you highlighted the extraordinary strides made over the past few years in developing instrumentation and other analytical tools that have vastly improved the ability to evaluate follow-on biologicals. Please identify for the Subcommittee the type of new analytical tools now available to industry and the Agency to conduct rigorous evaluations of follow-on biologics.

Answer. Over the last several years there have been many advances in analytical tools that have improved the ability to evaluate follow-on Biologicals.

Electrospray, matrix assisted laser desorption (ES–MS), and fast atom bombardment mass spectrometry (MALDI–TOF) have been use in conjunction with advances in separation technologies (Reverse Phase-High Performance Liquid Chromatography (RP–HPLC), Ion Exchange Chromatography, Hydrophobic Interaction Chromatography, Affinity Chromatography, and Size Exclusion Chromatography) to identify protein and carbohydrate heterogeneities and are very powerful tools for characterizing variations in a protein that are typically present in a single product.

Recent advances in mass spectrometry (time of flight, fourier transform) have greatly improved the resolving powers of the technology and now provide the capability to resolve to within a 1 Da mass accuracy, the mass of a protein. In conjunction with powerful deconvulution software, this technology allows for very accurate mass data and a more comprehensive assessment of the carbohydrate profiles. This technology has resulted in a new approach called "top down" that allows for the analysis of intact proteins. In contrast, the traditional approach analyzes protein fragments generated by digestion with proteases, making it difficult to provide assurance that minor modifications to the protein have been identified.

Protein aggregates can compromise the quality of a product as it relates to its safety and efficacy and are thought to be the most important product characteristic in generating immune responses. Such aggregates have typically been analyzed by size exclusion chromatography (SEC), an analytical method with limitations that result in the detection of only a very narrow spectrum of aggregates that can form in a protein product. Technological advances in a number of other analytical methods such as sedimentation velocity obtained by analytical ultracentrifugation and field flow fractionation can detect a much wider spectrum of aggregates, many of which are not detected by SEC.

Advances in gel electrophoresis primarily various forms of capillary electrophoresis, now provide excellent resolution between protein species which differ slightly in net charge and can be coupled to various detention methods (UV, fluorescence, MS) for enhanced product characterization.

Surface plasmon resonance technology monitors molecular interaction in real time and allows for the accurate detection and quantification of the on and off rates (kinetic rate constants) of protein-to-protein interactions. This technology has been applied to the design of immunoassays used for the detection of host antibodies formed against biotechnology products and to the characterization of mAB product interactions with their therapeutic target.

Advances in the understanding of signal transduction mechanisms for many protein products have provided for the development of more precise in vitro bioassays that monitor an early event in the biological function of a protein rather then a cellular response, such as cell growth, that is subject to greater variability in outcomes.

Protein products are not rigid structures and frequently the ability to flex and change conformations is critical to a protein's function. This property is difficult to detect by convention physicochemical techniques. However, advances in scanning probe microscopy particularly Atomic Force Microscopy (AFM), facilitate the mapping of biological samples to three-dimensional images and are capable of detecting multiple conformations. AFM-generated surface topology maps can portray in explicit detail the surface features of proteins and DNA. The application of this technology is broad and includes the study of protein and DNA structure, protein folding/unfolding, protein-to-protein interactions, protein-to-DNA interactions, enzyme catalysis and protein crystal growth.

Dynamic light scattering and multi-angle light scattering (LS) are beginning to be used in conjunction with advances in separation systems such as field flow fractionation and size exclusion chromatography. LS can provide absolute molecular weight, root-mean square radius and hydrodynamic radius of individual species of product.

Microcalorimetry allows one to assess the thermodynamic profile of a protein, which provides a measurement of the structural stability of the protein product or interactions with other proteins. The method can determine affinity constants, enthalpy, entropy, heat capacity, Gibbes free energy and the number of binding sites, parameters that help characterize proteins but have not been routinely employed in the biotech industry.

Fluorescence spectroscopy has been useful in monitoring flexibility of proteins and conformational stability.

Nuclear Magnetic Resonance Spectroscopy (NMR) has traditionally been used to identify small molecules and their structures are now being applied to solving the structure of much larger and more complex biological macromolecules.

Question. Please outline for the Subcommittee the history of FDA's regulation of biologicals, the range and volume of biological approvals issued by the Agency over the course of that history, and any other factors you consider relevant to FDA's vast

scientific expertise that is being applied to development of the draft Guidance and that ultimately would be brought to bear in evaluating follow-on biologicals.

Answer. The regulation of biologics began in the United States in 1902, when Congress passed the Virus, Serum and Antitoxin Act (also known as the Biologics Control Act of 1902 and as the Virus Toxin Law). This law was enacted following the deaths of ten children who had received injections of diphtheria antitoxin contaminated with tetanus. In 1901, there was a serious epidemic of diphtheria resulting in a great demand for the diphtheria antitoxin. At the time, there was no requirement for safety testing and none was performed, and the manufacturing process was not controlled properly. The tetanus contamination was traced to an infected horse whose serum was used in producing the antitoxin.

The 1902 Act required biologics to be manufactured in a manner that assured safety, purity, and potency. Provisions of the Act included:

—Establishment license requirements;
—Product license requirements;
—Labeling requirements;
—Inspection requirements;
—Suspension/revocation of licenses; and,
—Penalties for violations.

The responsibility for implementing this new law was given to the Hygienic Laboratory of the Public Heath Service (PHS). In 1903, PHS issued regulations that included requirements that inspections would be unannounced and licenses were to be issued and re-issued on the basis of an annual inspection. The 1902 Act was amended in 1944. One change included a requirement that a biological license could be issued only upon demonstration that the product and the establishment met standards to ensure the continued safety, purity and potency of such products. This evaluation was to be made during pre-licensure inspections. These provisions are codified in section 351 of the PHS Act (42 U.S.C. 262). Another change that occurred at this time was the focal point for administering the Act. This responsibility was given to the National Institute of Health's National Microbiological Institute. Changes in responsibility for regulating biological products under the PHS Act occurred in the mid-1950 with the advent of polio vaccines. From 1955 to 1972, biologics were regulated within the National Institutes of Health (NIH), in the Division of Biologics Standards (DBS). In 1972, biologic regulation was transferred to the FDA's Bureau of Biologics.

After this transfer to the FDA began a merger of the regulatory requirements of the PHS Act and the Federal Food, Drug and Cosmetic (FD&C) Act (21 U.S.C.). Biologics were viewed as biological products under the PHS Act, and as drugs under the FD&C Act, subject to inspection under the Good Manufacturing Practices (GMP) regulations for drugs. The reagent manufacturers were also inspected under drug GMPs because there were no device regulations until 1976. Among the several changes that occurred, blood banks were required to register with the FDA and GMPs for blood and blood products were promulgated. Today one of the major responsibilities of FDA is to ensure the safety of the Nation's blood supply.

In 1982, the FDA merged the Bureau of Biologics and the Bureau of Drugs into the Center for Drugs and Biologics. After a subsequent reorganization the responsibility for biologics regulation was placed under the Center for Biologics Evaluation and Research (CBER). The responsibilities for regulating biological products has grown and become more complex from its beginning in 1902, when technologies for producing biological products were in their infancy and the primary role was vaccine regulation. Today the regulation of a wide variety of novel biological products and their use as therapeutics requires knowledge of new scientific developments and concepts of research in the relevant biological disciplines. The therapeutic biological products that the FDA regulates are on the leading edge of technology. Rapid scientific advances in biochemistry, molecular biology, cell biology, immunology, genetics, and information technology are transforming drug discovery and development, paving the way for unprecedented progress in developing new medicines to conquer disease.

As a representative sample of the range and volume of biological products approved, we offer below the fiscal year 2003 approvals. CBER's fiscal year 2003 major approvals include all approvals for original new BLAs (except those for blood banking), and other approvals for original biologic, drug, or device applications or supplements (e.g., for new/expanded indications, new routes of administration, new/improved tests, new dosage formulations and regimens). Although most of the Office of Therapeutics Research and Review's applications were transferred to the Center for Drug Evaluation and Research on June 30, 2003, all major BLA approvals are included in this list for both centers.

[The information follows:]

BIOLOGICS LICENSE APPLICATIONS

Tradename/Proper Name	Indication for Use	Manufacturer
Pegasys Peginterferon alfa-2a	Treatment of adults with chronic hepatitis C who have compensated liver disease and who have not been previously treated with interferon alfa.	Hoffmann-La Roche Inc. Nutley, NJ
COBAS Ampliscreen HCV Hepatitis C Virus (Hepatitis C Virus/Polymerase Chain Reaction/Blood Cell Derived).	For the detection of HCV RNA, in human plasma.	Roche Molecular Systems, Inc. Pleasanton, CA
Pediarix DTaP & Hepatitis B (Recombinant) & Inactivated Polio Virus Vaccine.	Combination vaccine for childhood immunization.	GlaxoSmithKline Biologicals Rixensart, Belgium
COBAS Ampliscreen HIV–1 Human Immunodeficiency Virus Type 1 (HIV–1/Polymerase Chain Reaction).	For detection of Human Immunodeficiency Virus (HIV–1) in human plasma using Polymerase Chain Reaction.	Roche Molecular Systems, Inc. Pleasanton, CA
Aralast Alpha-Proteinase Inhibitor (Human)	Chronic replacement therapy (augmentation) in patients having congenital deficiency of Alpha-1-Proteinase Inhibitors with clinically evident emphysema.	Alpha Therapeutic Corporation Los Angeles, CA
HUMIRA Adalimumab	Reducing signs and symptoms and inhibiting the progression of structural damage in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more disease modifying antirheumatic drugs (DMARDs).	Abbott Laboratories Abbott Park, IL
Amevive Alefacept	Treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy.	Biogen, Inc. Cambridge, MA
Crosseal Fibrin Sealant (Human)	Adjunct to hemostasis during liver surgery.	OMRIX Biopharmaceuticals, Ltd. Fairfax, VA
Peroxidase Conjugate ORTHO Antibody to HBsAG ELISA Test System 3 Antibody to Hepatitis B Surface Antigen (Mouse Monoclonal) Enzyme-Linked Immunosorbent Assay (ELISA) (Antibody to HBsAg/Enzyme Immuno Assay (EIA), Version 3.0/Monoclonal).	Detection of hepatitis B surface antigen in human serum or plasma as a screening test and an aid in the diagnosis of potential hepatitis B infection.	Ortho-Clinical Diagnostics, Inc. Raritan, NJ
Fabrazyme agalsidase beta	For use in patients with Fabry disease to reduce globotriasylceramide (GL–3) deposition in capillary endothelium of the kidney and certain other cell types.	Genzyme Corporation Cambridge, MA

BIOLOGICS LICENSE APPLICATIONS—Continued

Tradename/Proper Name	Indication for Use	Manufacturer
Aldurazyme		
Laronidase	For treatment of patients with Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I) and for patients with the Scheie form who have moderate to severe symptoms.	Biomarin Pharmaceutical, Inc. Novato, CA
FluMist		
Influenza Virus Vaccine Live, Intranasal	For active immunization for the prevention of disease caused by influenza A and B viruses in healthy children and adolescents, 5–17 years of age, and healthy adults, 18–49 years of age.	MedImmune Vaccines, Inc. Mountain View, CA
XOLAIR		
Omalizumab	For adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.	Genentech, Inc. South San Francisco, CA
BEXXAR		
Tositumomab and Iodine I 131 Tositumomab	Treatment of patients with CD20 positive, follicular, non-Hodgkin's lymphoma, with and without transformation, whose disease is refractory to Rituximab and has relapsed following chemotherapy.	Corixa Corporation Seattle, WA
Zemaira		
Alpha-1-Proteinase Inhibitor (Human)	To use as chronic augmentation and maintenance therapy in individuals with Alpha-1-Antitrypsin Deficiency and evidence of emphysema.	Aventis Behring L.L.C. King of Prussia, PA
Advate		
Antihemophilic Factor (Recombinant), Plasma/Albumin Free Method.	Indicated in hemophilia A (classical hemophilia) for the prevention and control of bleeding episodes, and in the perioperative management of patients with hemophilia A.	Baxter Healthcare Corporation Westlake Village, CA
Genetic Systems HIV–1/HIV–2 Plus O EIA		
Human Immunodeficiency Virus Types 1 and 2 (HIV–1 and HIV–2/Enzyme Immunoassay (EIA)/ Recombinant and Synthetic).	For detection of antibodies to human immunodeficiency types 1 and 2.	Bio-Rad Laboratories, Inc. Hercules, CA
GAMUNEX		
Immune Globulin Intravenous (Human), 10 percent by Chromatography Process.	Indicated in primary humoral immunodeficiency and idiopathic thrombocytopenic purpura.	Bayer Corporation Berkeley, CA

BIOLOGICS LICENSE SUPPLEMENTS (FOR NEW INDICATIONS, NEW ROUTES OF ADMINISTRATION, NEW DOSAGE FORMS, IMPROVED SAFETY)

Tradename/Proper Name	Indication for Use	Manufacturer
Prevnar Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM197 Protein).	New indication for the prevention of otitis media.	Lederle Laboratories Division Pearl River, NY
Avonex Interferon beta-1a	Package insert revised to include updated information regarding serum neutralizing antibodies.	Biogen, Inc. Cambridge, MA
Pegasus Peginterferon alfa-2a	Combination therapy with Ribavirin, USP (COPEGUS), for the treatment of chronic Hepatitis C Virus infection in adults.	Hoffmann-La Roche Inc. Nutley, NJ
Aranesp Darbepoetin alfa	Darbepoetin alfa Albumin (human) formulation in single dose prefilled syringes for six dosage strengths (60, 100, 150, 200, 300 and 500 micrograms).	Amgen, Inc. Thousand Oaks, CA
Simulect Basiliximab	Addition of new single dose 10 mg strength of drug product.	Novartis Pharmaceuticals Corporation East Hanover, NJ
Avonex Interferon beta-1a	Package insert revised to include safety and efficacy data from a study of patients who experienced a single clinical exacerbation of multiple sclerosis and to provide a Medication Guide.	Biogen, Inc. Cambridge, MA
Betaseron Interferon beta-1b	To revise the Clinical Studies section to include data from two studies conducted in patients with secondary progressive multiple sclerosis (MS), also to update the Adverse Reactions and Warnings sections to include new safety information, and to provide a Medication Guide.	Chiron Corporation Emeryville, CA
Remicade Infliximab	For reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in patients with fistulizing Crohn's disease.	Centocor, Inc. Malvern, PA
Rebif Interferon beta-1a	Final pivotal study report that confirms the results of 48 week data.	Serono, Inc. Rockland, MA
Avonex Interferon beta-1a	HAS-free liquid formulation in a prefilled syringe as an alternate dosage form and to provide for a Medication Guide.	Biogen, Inc. Cambridge, MA

BIOLOGICS LICENSE SUPPLEMENTS (FOR NEW INDICATIONS, NEW ROUTES OF ADMINISTRATION, NEW DOSAGE FORMS, IMPROVED SAFETY)—Continued

Tradename/Proper Name	Indication for Use	Manufacturer
Dryvax Smallpox Vaccine, Dried, Calf Lymph Type	Active immunization against smallpox disease.	Wyeth Laboratories, Inc. Marietta, PA
Dryvax Smallpox Vaccine, Dried, Calf Lymph Type	Include new safety information for the recent reports of cardiac events and updated storage period for the vaccine after reconstitution from 15 days to 90 days.	Wyeth Laboratories, Inc. Marietta, PA
Infanrix Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed.	To include in the indication a fifth dose at 4–6 years of age after 4 prior doses of Infanrix.	GlaxoSmithKline Biologicals Rixensart, Belgium
Enbrel [1] Etanercept	To expand the rheumatoid arthritis indication to include improving physical function.	Immunex Corporation Seattle, WA
Enbrel [1] Etanercept	For reducing signs and symptoms in patients with active ankylosing spondylitis.	Immunex Corporation Seattle, WA
Enbrel [1] Etanercept	To expand the indication to include inhibiting the progression of structural damage of active arthritis in patients with psoriatic arthritis.	Immunex Corporation Seattle, WA
Kineret [1] Anakinra	To expand the indication to include slowing the progression of structural damage in moderately to severely active rheumatoid arthritis, in patients 18 years of age or older who have failed one or more DMARDs.	Amgen, Inc. Thousand Oaks, CA
Synagis [1] Palivizumab	To expand the indication to include children with hemodynamically significant congenital heart disease.	MedImmune,Inc Gaithersburg, MD

[1] OTRR product applications transferred to CDER on 6–30–03.

NEW DRUG APPLICATIONS

Tradename/Proper Name	Indication for Use	Applicant
TriCitrasol Anticoagulant Sodium Citrate Conc. 46.7 percent Trisodium Citrate, 30 mL Anticoagulant Sodium Citrate Solution	triCitrasol, after dilution of a rouleaux agent, is an anticoagulant used in granulocytapheresis procedures.	Cytosol Laboratories, Inc. Braintree, MA

NEW DRUG APPLICATIONS—Continued

Tradename/Proper Name	Indication for Use	Applicant
Anticoagulant Citrate Dextrose Solution, Solution A, U.S.P., (ACD–A). 50 mL, PN 6053 Anticoagulant Citrate Dextrose Solution (ACD)	To provide for the use of Anticoagulant Citrate Dextrose Solution, Solution A, U.S.P., (ACD–A) 50 mL for the extracorporeal processing of blood with Autologous PRP systems in production of platelet rich plasma (PRP) for in vitro use.	Cytosol Laboratories, Inc. Braintree, MA

SUPPLEMENTAL NEW DRUG APPLICATIONS

Tradename/Proper Name	Indication for Use	Applicant
Abbokinase Urokinase	Improvements in the manufacture and testing of the bulk drug substance and drug product, and withdrawal of the indication for coronary artery thrombosis indication (CAT) and the Open-Cath dosage strengths.	Abbott Laboratories Abbott Park, IL

DEVICE APPLICATIONS

Tradename	Description and Indication for Device	Applicant
OraSure OraQuick Rapid HIV–1 Antibody Test	For the detection of antibodies to HIV–1 in human fingerstick whole blood specimens.	OraSure Technologies Bethlehem, PA
MedMira Rapid HIV Test	For detection of HIV–1 and HIV–2 Antibodies.	MedMira labs Bayers Lake Halifax, Canada
Ortho ProVue, Software Version: 2.10	Modular, Microprocessor-controlled instrument designed to automate in vitro immunohematological testing to human blood utilizing the ID MTS/Gel Technology.	Micro Typing Systems Inc. Pompano Beach, FL
Vironostika HIV–1 Plus O Microelisa System	For the qualitative detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV–1), including Group O, in human specimens collected as serum, plasma, or dried blood spots.	BioMerieux, Inc. Durham, NC

DEVICE SUPPLEMENTS (FOR NEW INDICATIONS, IMPROVED SAFETY)

Tradename	Description and Indication for Device	Applicant
Calypte HIV–1 Urine EIA	HIV–1 Urine EIA to include changes to the black box warning statement.	Calypte Biomedical Corporation Alameda, CA

QUESTIONS SUBMITTED BY SENATOR CHRISTOPHER S. BOND

NUTRITIONAL GUIDELINES

Question. There is a linear relationship between high transfatty acid and high saturated fat intake and chronic disease. We also know that the consumption of foods high in these two elements likely contribute to the statistics on obesity. Does FDA intend to draft guidelines or standards for the consumption of these fats?

Answer. FDA issued on July 11, 2003 final rules to require that trans fatty acids be listed in mandatory nutrition labeling. Manufacturers must have this information in Nutrition Facts panels on all food packages entering interstate commence by January 1, 2006. On July 11, 2003, FDA also published an advance notice of proposed rulemaking (ANPRM) to solicit data and information that could be used to establish new nutrient content claims about trans fatty acids; to establish qualifying criteria for trans fat in current nutrient content and health claims; and to consider statements about trans fat, either alone or in combination with saturated fat and cholesterol to enhance consumers' understanding about such cholesterol-raising lipids and how to use the information to make healthy food choices. The agency has reopened the comment period to this ANPRM to receive comment on the Institute of Medicine's (IOM) December 2003 report on Dietary Reference Intakes in which the IOM included a suggested approach for establishing a daily value for trans fat. In addition, FDA has scheduled a Food Advisory Committee Nutrition Subcommittee meeting at the end of April 2004 to consider scientific questions related to saturated fat and trans fat that may help determine the agency's course for food labeling of these fats.

Question. Will FDA provide guidelines and or regulations to restaurants and other food manufacturers and—more importantly—provide them a roadmap to increasing the nutritional content and decrease saturated fat levels of their products?

Answer. An important goal of the Nutrition Labeling and Education Act of 1990 was to provide incentives to manufacturers to improve the nutritional composition of food products. Studies have shown that the implementing regulations, which required nutrition labeling on most packaged foods, resulted in a significant increase in the number of low- and reduced-fat products in the marketplace. We anticipate that the new labeling regulations requiring that trans fat be listed will have a similar effect, reducing total intake of trans fat. In fact, since publication of the final rule requiring the listing of trans fat, several food manufacturers and at least one major fast food restaurant chain have announced that they are changing the type of fats used in order to reduce levels of trans fats.

Question. Does FDA intend to provide guidelines and or regulations on the characteristics of healthy oils' that can be used in most food manufacturing to improve overall health and nutrition of those foods?

Answer. By requiring the saturated and trans fat content to be declared in Nutrition Facts panels on most packaged foods, FDA is providing an incentive for manufacturers to reduce the levels of those fats whose consumption is associated with increased levels of LDL-cholesterol.

Question. Does FDA have this authority?

Answer. Manufacturers may choose between different food ingredients to use in their food products, provided that such ingredients are safe for such use under the Federal Food, Drug, and Cosmetic Act (the Act). FDA has authority, under section 403(q) of the Act, to require nutrition labeling on packaged food products. Restaurant foods are exempt unless they make a nutrition claim.

Question. How will FDA ensure that as they move forward with trans-fat labeling that saturated fats will not come back into the diet?

Answer. Nutrition labeling will indicate the levels of both saturated fat and trans fat in most packaged foods. Consumer education programs will encourage consumers to look at both types of fats and to consider the combined total amount in making purchasing decisions.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

OBESITY

Question. Dr. Crawford, both USDA and FDA have recently announced new efforts to combat the increasing problem of obesity. FDA announced the "Calories Count" program, and USDA has money in several programs, including WIC, to help battle this problem. However, for all of the government's efforts, all of the money being put into this effort pales in comparison to the food industry's billions of dollars worth of advertising. How can the government successfully get its message out

when, at first glance, its efforts appear to be dwarfed by the food industry? How do your agencies compete with that?

Answer. In support of the President's *Healthier U.S.* initiative, the DHHS established a complementary initiative, *Steps to a Healthier U.S.,* which emphasizes personal responsibility for the choices Americans make for healthy behaviors. One aspect of this initiative focuses on reducing the major health burden created by obesity and other chronic diseases. Following DHHS' July 2003 Roundtable on Obesity and Nutrition, on August 11, 2003, FDA established an Obesity Working Group, or OWG, to prepare a report that outlines an action plan to cover critical dimensions of the obesity problem from FDA's perspective and authorities. This report was released on March 12, 2004.

There is no simple answer to the problem of obesity. Achieving success in reducing and avoiding obesity will occur only as a result of efforts over time by individuals as well as various sectors of our society. It should be noted, however, that most associations, agencies, and organizations believe that diet and physical activity should be addressed together in the fight against overweight and obesity.

The OWG report provides a range of short and long-term recommendations to address the obesity epidemic with a focus on a "calories count" emphasis for FDA actions. These recommendations are based on sound science and address multiple facets of the obesity problem under FDA's purview, including developing appropriate and effective consumer messages to aid consumers in making wiser dietary choices; establishing educational strategies and partnerships to support appropriate messages and teach people, particularly children, how to lead healthier lives through better nutrition; developing initiatives to improve the labeling of packaged foods with respect to caloric and other nutrition information; encouraging and enlisting restaurants in efforts to combat obesity and provide nutrition information to consumers, including information on calories, at the point-of-sale; developing new therapeutics for the treatment of obesity; designing and conducting effective research in the fight against obesity; and continuing to involve stakeholders in the process.

Regarding food labeling, the OWG report contains several recommendations based on sound science. I will provide these recommendations for the record.

[The information follows:]

Publish an advance notice of proposed rulemaking, or ANPRM, to seek comment on the following:

—How to give more prominence to calories on the food label, for example, increasing the font size for calories, including a column in the Nutrition Facts panel of food labels for percent Daily Value for total calories, and eliminating the listing for calories from fat;

—Whether to authorize health claims on certain foods that meet FDA's definition of "reduced" or "low" calorie. An example of a health claim for a "reduced" or "low" calorie food might be: "Diets low in calories may reduce the risk of obesity, which is associated with type 2 diabetes, heart disease, and certain cancers."

—Whether to require additional columns on the Nutrition Facts panel to list quantitative amounts and percent Daily Value of an entire package on those products and package sizes that can reasonably be consumed at one eating occasion—or declare quantitative amounts and percent Daily Value of the whole package as a single serving if it can reasonably be consumed at a single eating occasion; and,

—Which, if any, reference amounts customarily consumed of food categories appear to have changed the most over the past decade and hence require updating.

In addition, FDA will file and respond in a timely way to petitions the agency has received that ask FDA to define terms such as "low," "reduced," and "free" carbohydrate; and provide guidance for the use of the term "net" in relation to carbohydrate content of food—these petitions were filed on March 11, 2004.

FDA will also encourage manufacturers to use dietary guidance statements, an example of which would be, "To manage your weight, balance the calories you eat with your physical activity." In addition, the Agency will encourage manufacturers to take advantage of the flexibility in current regulations on serving sizes to label as a single-serving those food packages where the entire contents of the package can reasonably be consumed at a single eating occasion and encourage manufacturers to use appropriate comparative labeling statements that make it easier for consumers to make healthy substitutions.

FDA believes that if the report's recommendations are implemented they will make a worthy contribution to confronting the Nation's obesity epidemic and helping consumers' lead healthier lives through better nutrition.

FDA also believes that the regulatory scheme for claims in food labeling, whether health claims, nutrient content claims, or other types of claims, are science based, and we continue to consider modifications to our regulations to keep up with recent scientific developments. A benefit of standardized, science-based terminology, as with other terms that FDA has defined that consumers may use to make health-based dietary choices—e.g., terminology concerning fat content-, is that it allows consumers to compare across products and it encourages manufacturers to compete based on the nutritional value of the food. However, FDA does not regulate television and other media marketing of food products. Some of the modifications FDA is currently considering are described above in the list of topics to be covered by the ANPRM the agency intends to issue.

With respect to conveying the report's messages to the public, FDA believes that all parties, including the packaged food industry, restaurants, academia, and other private and public sector organizations in addition to government agencies at all levels, have an essential role to play. On April 22, 2004, FDA's Science Board focused on specific recommendations from the OWG report. These recommendations call on FDA to work through a third-party facilitator to engage all involved stakeholders in a dialogue on how best to construct and convey obesity messages in the restaurant setting and in the area of pediatric obesity education.

This approach is one example of how the Agency intends, by means of public and private partnerships, to leverage its ability to convey appropriate messages on obesity to the public with the goal of changing behavior and ultimately reversing obesity trends in the United States.

IMPORT INSPECTIONS

Question. Dr. Crawford, the FDA budget this year includes a $7 million increase to fund 97,000 food import examinations. This is a big increase in inspections over any previous year—still, however, less than one percent of all of the food imported into this country will be inspected. How would you respond to charges that you still aren't inspecting nearly enough imported food, especially in light of events during the past year where bad food has gotten in and people have died? How do we ensure consumers that their food is indeed safe?

Answer. FDA is appreciative of the additional funding we have received for the inspection of domestic firms and for inspections of imported foods. FDA believes it is more effective to focus our resources in a risk-based manner than to focus simply on increasing the percentage of imported food shipments that are physically inspected. It is important to note that every shipment of FDA-regulated food which is entered through Customs and Border Protection as a consumption entry is electronically reviewed by FDA's Operational and Administrative System for Import Support to determine if it meets identified criteria for further evaluation by FDA reviewers and physical examination and/or sampling and analysis or refusal. This electronic screening allows FDA to concentrate its limited inspection resources on high-risk shipments while allowing low-risk shipments to proceed into commerce.

Due to constantly changing environments of operation, e.g., counterterrorism and BSE, our domestic inspection and import strategy cannot be defined in terms of a percentage of coverage through inspections, physical examinations and sample analyses. It needs to be a flexible blend of the use of people, technology, information and partnerships to help protect Americans from unsafe imported products. Accordingly, the Agency is developing and using strategies for mitigating risks prior to importation through partnerships and initiatives based on best practices and other science based factors relevant to the import life cycle, i.e., from foreign manufacturer to the U.S. consumer. Recently this principle has been applied in the "Canadian Facility Voluntary Best Management Practices for Expediting Shipments of Canadian Grains, Oilseeds and Products to the United States" implemented February 24, 2004, and designed to mitigate the potential of mammalian protein prohibited from being fed to cattle or other ruminants under BSE-prevention regulations promulgated by CFIA and FDA.

Another piece of the long term solution to a higher level of confidence in the security and safety of food products lies in information technology that will merge information on products and producers with intelligence on anticipated risks to target products for physical and laboratory examination or refusal. This strategy would rely on data integrity activities that reduce the opportunity for products to be incorrectly identified at ports. It would also rely on cooperation from producers so that FDA can identify sources that are unlikely to need physical testing. However, even with such targeting, improvements are limited by the available methodologies for assessing threat agents and our ability to predict which tests ought to be used.

We are ramping up our food inspections, but we recognize that we also need to inspect smarter, not just inspect more. That is why FDA is making significant investments in technology and information resources such as the development of the Mission Accomplishment and Regulatory Compliance Services System, MARCS. MARCS is a comprehensive redesign and reengineering of two core mission critical systems at FDA: FACTS and the Operational and Administrative System for Import Support, OASIS. OASIS supports the review and decision making process of products for which entry is sought into the United States. We are using funds to work to further improve targeting and using force multipliers such as IT.

FDA also has a proof of concept project, called "Predict," with New Mexico State University under a Department of Defense contract which is being designed to enhance agency capability to rapidly assess and identify import entries based on risk using relevant information from various sources including regulated industry, trade, other Federal, State, and local entities, and foreign industry and governments. This project, if successful, will greatly enhance FDA's capability to be smarter in directing field activities on products of greater risk to public health and safety. The proof of concept project is projected to be completed in the Fall of 2004. The relentless growth in the volume of domestic as well as imported food products, which are increasingly in "ready for consumer sale packaging." Food imports are now growing at 19 percent per year. FDA needs to use all the potential tools available to improve its efficiency in food security and safety coverage.

In addition, FDA has several strategic initiatives to enhance safety. One of these is "Agency Initiatives to Improve Coverage," which includes the creation of the Southwest Import District to better coordinate import activities on the southern border. Another is reciprocal FDA and U.S. Customs and Border Protection training to improve product integrity of goods offered for import and increase enforcement actions by Customs to deter willful violations of U.S. laws and regulations. While foreign inspections and border operations provide some assurance that imported foods are safe, the agency continues to work to foster international agreements and harmonize regulatory systems. For instance, we actively participate in the Canada/U.S./Mexico Compliance Information Group, which shares information on regulatory systems and the regulatory compliance status of international firms to protect and promote human health.

It is very important that American consumers trust the safety of the food supply. FDA has made fundamental changes in how we implement our mission of protecting the food supply, so that all Americans can have confidence that their food has been handled under secure conditions that provide assurance of its safety.

FDA FOIA POLICIES

Question. Dr. Crawford, my office has been working with a non-profit patient advocacy group, the TMJ Association, in their efforts to have two FOIA requests that are well over a year old responded to. Their original FOIA request was made on November 1, 2002 (request number 02017071), more than 17 months ago, and the subsequent request was made on March 25, 2003 (request number 03004361). They have not yet received the information requested, and have been unable to get a date commitment by FDA as to when the information will be provided. It is my understanding that they have been informed that FOIA requests are severely backlogged, and the FDA has no idea when they will be able to process their request. What is the current backlog for FOIA requests?

Answer. As of April 28, 2004, FDA has 19,369 pending FOIA requests—17,555 have been pending more than 20 days and 1,814 have been pending 20 days or less. The Denver District Office is responsible for responding to the two requests from the TMJ Association. As of April 28, 2004, Denver District Office has 369 pending FOIA requests—357 requests have been pending more than 20 days, and 12 requests have been pending 20 days or less.

Question. How many FDA staff are responsible for handling these requests? Is this their sole responsibility, or do they have other responsibilities as well?

Answer. For fiscal year 2003 the total number of personnel responsible for processing FOIA requests was 91 FTE, 75 full time employees, and 16 FTE work years representing personnel with part-time FOIA duties in addition to other responsibilities.

Question. Does FDA need additional staff or resources in order to process these requests on a timely basis?

Answer. In some agency components FOIA is a collateral duty. For example, in most FDA field offices, Compliance Officers whose primary responsibilities are related to the Agency's regulatory enforcement activities also perform FOIA duties as

permitted by time and regulatory workload. Additional staff devoted to FOIA could shorten the amount of time for processing requests.

Question. What do you believe is a reasonable length of time for a group to wait for an information request to be processed and responded to?

Answer. Requests are processed by the agency component that maintains the requested records. There are a number of factors that must be considered in order to predict a reasonable amount of time for a request to be processed. Those factors include the volume of requests received by the component, the complexity of requests received, the amount of time required to search for records, the amount of time require to review the records to determine whether information is releasable under FOIA, and the resources available to process requests.

Question. What is the average length of time it takes to process a FOIA request? Can you please explain the severe delay in processing this specific one, which has taken over 2 years and apparently has no end in sight? Can you please provide me a timeframe within which the FDA will respond to these two particular FOIA requests?

Answer. Under the Electronic Freedom of Act Amendments of 1996, agencies are permitted to establish multiple tracks for processing FOIA requests based on the complexity of the requests and the amount of work and time required to process requests. Some FDA components have established multiple processing tracks. Requests are processed on a first in, first out basis within each track. The median number of days to process requests in the simple processing track is 19 days. The median number of days to process requests in the complex processing track, for more complicated requests, is 363 days. For requests that are not processed in multiple processing tracks, the median number of days to process is 44 days.

Due to a heavy load of regulatory cases in the Denver District Office that must be handled by the Compliance Officers in addition to staff shortages, FOIA work in the Denver District is being performed by one individual on a part-time basis. This has resulted in a significant backlog of FOIA requests. The Denver District Office expects to fill request 02–17071 from the TMJ Association in six months, and request 03–4361 in one month.

Question. What additional efforts can this group undertake in order to speed up their request?

Answer. The Denver District Office expects to fill request 02–17071 from the TMJ Association in 6 months, and request 03–4361 in one month.

In addition, the Denver District is reviewing and evaluating its FOIA workload and will develop a strategy aimed at reducing the backlog of FOIA requests.

Question. What is the FDA's policy on charging for FOIA requests made by non-profit patient advocacy groups?

Answer. The FOIA sets forth criteria that agencies must follow with respect to charging for processing FOIA requests. Non-profit organizations are considered Category III requesters. Such requesters receive 100 pages of duplication and 2 hours of search at no charge. If the number of pages exceed 100 and/or if the amount of search time exceeds 2 hours, Category III requesters are charged based on the FOIA fee schedule of the Department of Health and Human Services. The fee for duplication is $.10 per page, and the fee for search is based on the grade level of the individual who processes the request. I will be happy to provide the current grade rates for the record.

[The information follows:]

Current Grade Rates

GS–1 through 8—$18.00 per hour
GS–9 through 14—$36.00 per hour
GS–15 and above—$64.00 per hour

In addition, requesters may make a request for waiver or reduction of fees if their request meets the following criteria: disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government; and, disclosure is not primarily in the commercial interest of the requester.

IMPLICIT PRE-EMPTION

Question. Adverse reactions to prescription drugs and other medicines take the lives of more than 100,000 Americans each year, and millions more are seriously injured. For many years, state tort laws have enabled some victims to receive compensation for their injuries. It has been brought to my attention that the Food and Drug Administration (FDA) has stepped in to protect drug companies from liability in some of these lawsuits, potentially robbing individuals of their only means of compensation. FDA's actions are even more troubling when you consider that these

lawsuits have other important purposes, such as deterring future bad behavior and providing the American public with access to important health and safety information. How many times has the FDA interfered in lawsuits, arguing that implicit preemption prohibits a plaintiff from receiving compensation for their injuries? In how many of these cases has a court held that the plaintiff's tort claim was implicitly pre-empted by Federal law?

Answer. In the past several years, the Department of Justice (DOJ) has represented the United States in four cases involving state-law challenges to the adequacy of FDA-approved risk information disseminated for FDA-approved new drugs.[1] In each case, DOJ contended that the state-law claim was preempted by Federal law. In addition, in some cases, DOJ argued that the state-law claim was not properly before the court by operation of the doctrine of primary jurisdiction.[2]

The legal basis for preemption in these cases is FDA's careful control over drug safety, effectiveness, and labeling according to the agency's comprehensive authority under the FDCA and FDA implementing regulations. If state authorities, including judges and juries applying state law, were permitted to reach conclusions about the safety and effectiveness information disseminated with respect to drugs for which FDA has already made a series of regulatory determinations based on its considerable institutional expertise and statutory mandate, the Federal system for regulation of drugs would be disrupted. I will be happy to include information on the four cases for the record.

[The information follows:]

Bernhardt

In 2000, two individual plaintiffs filed product liability actions in a New York court against Pfizer, Inc., seeking a court order requiring the company to send emergency notices to users of the prescription antihypertensive drug CARDURA (doxazosin mesylate) and their physicians. The notices would have described the results of a study by a component of the National Institutes of Health (NIH) that, the plaintiffs alleged, demonstrated that Cardura was less effective in preventing heart failure than a widely used diuretic. FDA had not invoked its authority to send "Dear Doctor" letters or otherwise disseminate information regarding a drug that the agency has determined creates an "imminent danger to health or gross deception of the consumer." (21 U.S.C. 375(b).) The plaintiffs, nevertheless, filed a lawsuit under state common law seeking relief that, if awarded, would have pressured the sponsor to disseminate risk information that FDA itself had not disseminated pursuant to its statutory authority.

FDA's views were submitted to the Federal district court in the form of a Statement of Interest.[3] The Statement relied on the doctrine of primary jurisdiction. The Statement also took the position that the plaintiffs' request for a court order requiring the dissemination of information about NIH study results to users and prescribers of CARDURA was impliedly preempted. According to the Statement, the court order "would frustrate the FDA's ability effectively to regulate prescription drugs by having the Court substitute its judgment for the FDA's scientific expertise." The Statement also noted that, if the court granted the requested order, a direct conflict would be created between the information required to be disseminated by the court and the information required to be disseminated by FDA under the FDCA (in the form of the FDA-approved labeling).

The Statement contended that state law could not provide a basis for requiring a drug manufacturer to issue drug information that FDA had authority to, but did not, require. Importantly, the submission did not argue that the state-law claim was preempted because FDA had reached a determination that directly conflicted with the plaintiff's view. Nor did it assert that FDA had specifically determined that the information on the NIH study requested by the plaintiffs was unsubstantiated, false, or misleading. In this sense, the Statement of Interest in Bernhardt was the most aggressive, from a legal perspective, than the three subsequent DOJ submissions on FDA's behalf in preemption cases made during the present Administration.

The United States District Court for the Southern District of New York accepted the primary jurisdiction argument made on FDA's behalf. (*Bernhardt* v. *Pfizer, Inc.,*

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[1] FDA also periodically becomes involved, through the Department of Justice, in cases involving preemption of state-law requirements under the medical device provisions of the FDCA, which include an express preemption provision, 21 U.S.C. 360k(a).

[2] Primary jurisdiction allows a court to refer a matter to an administrative agency for an initial determination where the matter involves technical questions of fact and policy within the agency's jurisdiction. See, e.g., *Israel* v. *Baxter Labs., Inc.,* 466 F.2d 272, 283 (D.C. Cir. 1972); see also 21 CFR 10.60.

[3] Statement of Interest of the United States; Preliminary Statement, *Bernhardt* v. *Pfizer, Inc.,* Case No. 00 Civ. 4042 (LMM) (S.D.N.Y. filed Nov. 13, 2000).

2000 U.S. Dist. LEXIS 16963, *9 (whether the additional warnings sought by the plaintiffs were appropriate "is a decision that has been squarely placed within the FDA's informed expert discretion").) It did not address the preemption issue. The case was voluntarily dismissed on April 22, 2003.

Dowhal

In 1998, an individual plaintiff in California asked that State's attorney general to initiate an enforcement action against SmithKline Beecham and other firms marketing OTC nicotine replacement therapy products in California. (These products are marketed pursuant to an approved new drug application.) The plaintiff contended that the FDA-approved warnings for the defendants' products did not meet the requirements of a state statute called the Safe Drinking Water and Toxic Enforcement Act (Cal. Health & Safety Code § 25249.5 et seq.), also known as Proposition 65. From 1996 through 2001, FDA had repeatedly advised the defendants that they could be liable under the FDCA for selling misbranded products if they deviated from the FDA-approved warning labeling for their products. FDA also advised the state attorney general in writing in 1998 that the defendants' warning in the labeling clearly and accurately identified the risks associated with the products and, therefore, met FDA requirements under the FDCA. After receiving the letter, the attorney general declined to initiate enforcement action.

Nevertheless, in 1999, the individual plaintiff initiated a lawsuit of his own in California state court under Proposition 65's "bounty-hunter" provision, which empowers individuals to file enforcement actions under that statute on behalf of the people of the State of California. The lawsuit asked the court to award civil money penalties and restitution, and to issue an injunction requiring the defendants to disseminate warnings for their products that differed from the warnings required by FDA. In 2000, the plaintiff filed a citizen petition with FDA requesting that the agency require the defendants to change their warnings to reflect the language sought by the plaintiff in the lawsuit. FDA rejected the proposed language, determining that it lacked sufficient support in scientific evidence and presented a risk of mischaracterizing the risk-benefit profile of the products in a way that threatened the public health. Although the trial court found for the defendant, the California Court of Appeal rejected the defendant's contention that the plaintiff's claim was preempted under the FDCA, and allowed the lawsuit to proceed. (*Dowhal* v. *SmithKline Beecham Consumer Healthcare,* 2002 Cal. App. LEXIS 4384 (Cal. Ct. App. 2002), argued, Case No. S–109306 (Cal. Feb. 9, 2004).)

FDA's views were presented to the Court of Appeal of California in an amicus curiae ("friend of the court") brief and to the Supreme Court of California in a letter brief and an amicus brief.[4] All three documents explained that the warning language sought by the plaintiffs had been specifically considered and rejected by FDA as scientifically unsubstantiated and misleading. Including the language would, therefore, misbrand those products and cause the defendants to violate the FDCA. The documents explained, further, that principles of conflict preemption applied to the plaintiffs' claim because it was impossible for defendants to comply with both Federal and State law and because the state law posed an obstacle to the accomplishment of the full purposes and objectives of the FDCA.

The California Court of Appeal rejected the preemption argument. (*Dowhal* v. *SmithKline Beecham Consumer Healthcare,* 2002 Cal. App. LEXIS 4384, . . . 16–17 (Cal. Ct. App. 2002) (reversing trial court decision granting summary judgment for defendants on preemption grounds).) On April 15, 2004, the California Supreme Court reversed the appeals court decision, finding a direct conflict between FDA requirements and the state-law warning requirement advocated by the plaintiff. (*Dowhal* v. *SmithKline Beecham Consumer Healthcare*, 2004 Cal. LEXIS 3040.)

Motus

Also in 2000, an individual plaintiff sued Pfizer in a California court alleging, among other things, that the company had failed to fulfill its state common law duty to warn against the risk of suicide the plaintiff alleged was presented by ZOLOFT (sertraline HCl), an FDA-approved drug in the selective serotonin reuptake inhibitor (SSRI) class indicated to treat depression (among other things). On numerous occa-

[4] Letter from Robert D. McCallum, Jr., Ass't Attorney General, et al., to Frederick K. Ohlrich, Supreme Court Clerk/Administrator, *Dowhal* v. *SmithKline Beecham Consumer Healthcare LP*, et al., Case No. S–109306 (Cal. filed Sept. 12, 2002); Amicus Curiae Brief of the United States of America in Support of Defendants/Respondents SmithKline Beecham Consumer Healthcare LP, et al., *Dowhal* v. *SmithKline Beecham*, Case No. A094460 (Cal. Ct. App. filed Mar. 22, 2002); Amicus Curiae Brief of the United States of America in Support of Defendants/Appellants SmithKline Beecham Consumer Healthcare LP, et al., *Dowhal* v. *SmithKline Beecham*, Case No. S109306 (Cal. filed July 31, 2003).

sions, FDA had specifically considered and rejected such language for SSRIs as scientifically unsupportable and inconsistent with FDA determinations as to the safety and effectiveness of the products.

The United States District Court for the Central District of California (to which the case had been removed on the ground of diversity) rejected the defendant's preemption argument, allowing the lawsuit to proceed. (*Motus* v. *Pfizer Inc.,* 127 F. Supp. 2d 1085 (C.D. Cal. 2000).) The court later granted the defendant's motion for summary judgment on non-preemption grounds (196 F. Supp. 2d 984, 986 (C.D. Cal. 2001)), and the plaintiff appealed. DOJ submitted an amicus curiae brief to the United States Court of Appeals for the Ninth Circuit on FDA's behalf.[5] The brief's arguments were essentially the same as the arguments advanced in *Bernhardt.* In contrast to the situation in *Bernhardt,* however, in Motus, FDA had specifically considered, and rejected, the language requested by the plaintiff under state law. The appeals court affirmed the trial court's decision earlier this year (2004 U.S. App. LEXIS 1944 (9th Cir. February 9, 2004)).

In re PAXIL

In 2001, individuals filed suit in a California court on behalf of past or current users of PAXIL (paroxetine HCl) against the drug's manufacturer, GlaxoSmithKline (GSK), alleging that the company's direct-to-consumer (DTC) broadcast advertisements for the drug failed adequately to warn about the consequences of discontinuing the drug. In reviewing the new drug application for the drug, FDA had found no evidence that it was habit-forming and did not require GSK to address that risk in FDA-approved labeling. FDA did, however, require GSK to include in labeling statements regarding discontinuation syndrome, and the labeling consequently recommends that doctors gradually reduce dosages and monitor patients for syndrome symptoms. FDA reviewed proposed DTC advertisements GSK had submitted for Paxil that said that the drug was not habit-forming. The agency at no time determined that this statement was misleading. In August 2002, notwithstanding FDA's determination, the court issued a preliminary injunction prohibiting GSK from running DTC advertisements stating that Paxil is not habit-forming. (*In re Paxil Litigation,* 2002 U.S. Dist. LEXIS 16221 (C.D. Cal. Aug. 16, 2002).)

On reconsideration, the court declared that the preliminary injunction challenged only "FDA's . . . determination that the public is not likely to equate the words 'not habit forming' as used in direct[-]to[-]consumer advertisements with no withdrawal symptoms." According to the court, "The question of how members of the general public are likely to interpret (or misinterpret) a statement is within one of the courts' core competencies." Declaring itself "unwilling to blindly accept FDA's ultimate determination here," the court rejected the defendants' preemption and primary jurisdiction arguments. It nevertheless denied the injunction on the ground that the plaintiff was not likely to succeed in demonstrating that "non-habit forming" statement in the advertisement is misleading. Thus, although the court ultimately declined to award the injunctive relief sought by the plaintiff, it continued to distinguish between FDA's determinations as to the adequacy of drug warnings under Federal law, and its own view of warnings adequacy under state common law. (*In re Paxil Litigation,* 2002 U.S. Dist. LEXIS 24621 (C.D. Cal. Oct. 16, 2002).)

DOJ submitted to the court a Statement of Interest and a brief asserting preemption.[6] The Statement of Interest contended that a court order requiring GSK to remove the "non-habit-forming" claim from its advertisements for Paxil would be inconsistent with FDA's determination that the company's advertisements were proper and that Paxil is not, in fact, "habit-forming." The brief contended that the court should find the plaintiff's state-law request for a court order preempted because it poses an obstacle to achievement of the full objectives of Congress "by attempting to substitute th[e] Court's judgment for FDA's scientific expertise." As the brief pointed out, FDA had specifically reviewed the advertisements, made suggestions concerning the proper manner of presenting information relating to whether Paxil is "habit-forming," and, in the exercise of its scientific and medical expertise, found the advertisements acceptable. The brief also included a primary jurisdiction argument. The court reversed its earlier award of an injunction prohibiting the manufacturer from running advertisements that had been reviewed and approved by FDA,

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[5] Amicus Brief for the United States in Support of the Defendant-Appellee and Cross-Appellant, and in Favor of Reversal of the District Court's Order Denying Partial Summary Judgment to Defendant-Appellee and Cross-Appellant, *Motus* v. *Pfizer*, Case Nos. 02–55372 & 02–55498 (9th Cir. filed Sept. 3, 2002).

[6] Statement of Interest of the United States of America, In re PAXIL Litigation, Case No. CV 01–07937 MRP (CWx) (C.D. Cal. filed August 20, 2002); Brief of the United States of America, In re PAXIL Litigation, Case No. CV 01–07937 MRP (CWx) (C.D. Cal. filed Sept. 4, 2002).

but the reversal was based on a ground other than preemption. (*In re Paxil Litigation,* 2002 U.S. Dist. LEXIS 24621 (C.D. Cal. 2002).)[7]

Conclusion

As these cases illustrate, courts entertaining lawsuits filed under state law do not always defer to FDA on matters that Congress has placed squarely within the agency's authority. In FDA regulatory areas characterized by comprehensive regulation and requiring a careful and expert evaluation of scientific data and public health issues, state coregulation can stand as an obstacle to or directly conflict with the agency's administration of its statutory mandate. Preemption is the constitutionally prescribed mechanism for resolving these conflicts.

The practice of citing preemption and primary jurisdiction under the FDCA in litigation in which the United States is not a party is well-established and substantially predates the current Administration. DOJ and FDA participation in these cases is unusual. In the current Administration, DOJ has participated in private state-law actions on FDA's behalf only following a judicial finding that the action should proceed, and only to address a state-law finding that, left undisturbed, would undermine FDA's execution of its statutory mission or directly conflict with Federal law. Responsibility for making final decisions whether to make submissions in private lawsuits, on preemption, primary jurisdiction, or any other issue, rests with the Department of Justice—not FDA itself.

Question. These arguments conflict with long-standing FDA policy. The law appears to contradict what the FDA has argued. What motivated FDA to change its policy?

Answer. The Government's participation in cases arising under state-law and presenting preemption issues is consistent with past FDA practice and with the pertinent law.

The principal enabling statute of the Food and Drug Administration is the Federal Food, Drug, and Cosmetic Act, FDCA. Under this statute, FDA has broad authority to protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled, and that drugs and medical products are safe and effective. (See 21 U.S.C. § 393(b)(2)(A)–(C).) By operation of the Supremacy Clause of the United States Constitution (U.S. Const. Art. VI, clause 2), the FDCA nullifies conflicting requirements established by the States in legislation, regulations, or common law. (See *Gibbons* v. *Ogden,* 22 U.S. (9 Wheat.) 1, 211 (1824) (Marshall, C.J.).)

In the past, FDA has addressed conflicting state requirements in the context of rulemaking. In 1982, for example, FDA promulgated regulations requiring tamper-resistant packaging for over-the-counter drugs. In the preamble accompanying the regulations, FDA stated its intention that the regulations preempt any state or local requirements that were "not identical to . . . [the rule] in all respects." (47 FR 50442, 50447; Nov. 5, 1982.) Similarly, in 1986, FDA issued regulations requiring aspirin manufacturers to include in labeling a warning against use in treating chicken pox or flu symptoms in children due to the risk of Reye's Syndrome. In the accompanying preamble, FDA said the regulations preempted "State and local packaging requirements that are not identical to it with respect to OTC aspirin-containing products for human use." (51 FR 8180, 8181; Mar. 7, 1986.) In 1994, FDA amended 21 CFR 20.63 to preempt state requirements for the disclosure of adverse event-related information treated as confidential under FDA regulations. (59 FR 3944; Jan. 27, 1994.)

In addition, for many years, conflicting state requirements have been addressed by FDA through case-by-case participation in selected lawsuits to which the United States has not been a party. Because FDA lacks independent litigating authority, this participation has been by the Department of Justice (DOJ) on FDA's behalf. The practice of addressing conflicting state requirements through participation in litigation dates back many years. For example, DOJ participated on FDA's behalf in favor of preemption in both *Jones* v. *Rath Packing Company,* 430 U.S. 519 (1977), and *Grocery Manufacturers of America, Inc. v. Gerace,* 755 F.2d 993 (2d Cir. 1985). In addition, as discussed in our response to the previous question on preemption, FDA has recently participated in several cases involving state-law requirements for the communication of risk information for prescription drugs. Of note, the first—and most aggressive, from a legal perspective—of these submissions occurred during the previous Administration—*Bernhardt* case included in materials for the record.

[7] In December 2003 (296 F. Supp. 2d 1374), the litigation, consisting of twelve action in eleven Federal judicial districts, was centralized for pretrial proceedings in the United States District Court for the Central District of California.

NARMS

Question. What is the total amount of funding for NARMS, and from what account does it come?

Answer. The total amount of funding for NARMS in fiscal year 2004 is $7.634 million. This funding is located in the Salaries and Expenses, or S&E, account.

Question. How much is FDA giving to USDA and CDC in fiscal year 2005? How does that compare to fiscal year 2004? Please describe what factors are used to determine the division of funds.

Answer. At this time, FDA has not determined the exact funding for CDC and USDA for NARMS for fiscal year 2005 but plans to make decisions by Fall 2004. In fiscal year 2004, FDA funding on NARMS will be reduced due to government-wide rescissions. In fiscal year 2004, FDA provided funds of approximately $1.6 million to USDA and $2 million to CDC. It is important to point out that a large portion of the funds provided to CDC is given to the states for the collection, isolation and identification of bacterial isolates, which are then shipped to CDC and the Food and Drug Administration's Center for Veterinary Medicine—NARMS retail arm—for susceptibility testing. In determining the funds provided to CDC and USDA, we analyze the entire NARMS program, including the retail food arm of NARMS, and strive to fill in data gaps and avoid duplication of organisms to be tested.

Question. How much NARMS money is currently being spent in foreign countries, specifically Mexico? How is this money being used?

Answer. FDA is not spending any current year NARMS funding in Mexico or other foreign countries.

Question. Does USDA or CDC spend any of their NARMS money in foreign countries?

Answer. In fiscal year 2004 FDA is providing USDA and CDC, $1.6 million and $2 million respectively. FDA does not keep detailed records of USDA and CDC funding for NARMS.

COUNTERFEIT DRUGS

Question. In February, FDA released a report on combating counterfeit drugs. Several new technologies were mentioned that could be used to this effect, including Radiofrequency Identification tagging, color shifting inks, and holograms. Specifically regarding color shifting inks, which I understand are currently available, has FDA taken any action, or do you have any plans to pursue this option?

Answer. It is true that color shifting ink technology is currently available for use on drug packaging and labeling. However, we heard uniformly from all stakeholders that this technology is expensive and requires significant investment of resources and time prior to implementation. Due to the wide variety of products, packaging, and labeling on the market, we heard from manufacturers, wholesalers, and retailers that the decision to use color shifting inks, or any other authentication technology, should be made by the manufacturer after a manufacturer initiated product risk assessment. Without such an analysis, use of color-shifting ink, or other authentication technology, could lead to an unnecessary increase in the cost of drugs to consumers. For example, we heard that color-shifting ink could be appropriate for use on a very expensive, high volume brand name drug product that is likely to be counterfeited, but not on a generic or low volume drug product that is less likely to be counterfeited.

Based on our discussions with manufacturers, we estimate that it would take a minimum of six to twelve months to implement a technology such as color shifting ink from the time a decision is made to use the authentication technology on the packaging and/or labeling of a drug product. It could take longer if the technology, e.g., color-shifting ink, is used on the product itself because safety studies might have to be performed to ensure that the technology, e.g., the ink, does not affect the safety or stability of the product.

ANIMAL DRUG COMPOUNDING

Question. Dr. Crawford, on February 10, I submitted a letter to Dr. McClellan regarding FDA's new Compliance Policy Guidelines, issued July 14, 2003, regarding animal drug compounding. I received a response from FDA on March 31st, and I thank you for that. However, I do have a few more questions in light of the response.

First, the letter stated that FDA issued the CPG for immediate implementation because of the "urgent need to explain how it intended to exercise its enforcement discretion regarding compounded drugs for animal use in light of *Thompson* v. *Western States Medical Center*." However, this case dealt only with compounding in

human drugs, not animal drugs. How does this create an urgent need to deal with animal drugs?

Answer. After the *Western States* decision, FDA revised its enforcement policy on pharmacy compounding of human drugs. FDA was concerned that without updated guidance regarding compounding of animal drugs, the public would remain uncertain about whether and how FDA would change its enforcement policy with respect to compounded animal drugs. In addition, agency staff would lack clear guidance on enforcement matters.

As FDA stated in its letter, although prior public comment was not sought in this case, pursuant to the good guidance practices regulations the public was invited to comment on the CPG when it was issued and may comment on it at any time (68 FR 41591 (July 14, 2003)). FDA has been reviewing those comments and will revise the guidance as appropriate upon completion of our review.

Question. Second, the response states that two Federal appeals court decisions have held that "the Federal Drug & Cosmetic Act does not permit veterinarians to compound unapproved finished drugs from bulk substances, unless the finished drug is not a new animal drug. These cases support FDA's position that new animal drugs that are compounded from bulk substances are adulterated under the FD&C Act and may be subject to regulatory action." I have been informed that the cases cited deal only with veterinarians compounding drugs, not pharmacists. Why do you limit pharmacists as well as veterinarians? Is this supported by any congressionally-enacted statutory authority, legislative history or case law?

Answer. The principle established by the courts applies equally to compounding by pharmacists and veterinarians.

Veterinary medicine has not traditionally utilized the services of compounding pharmacies to the extent that they have been utilized within human medicine. The increasing activities and presence of compounding pharmacies in veterinary medicine is a relatively recent development.

The Federal Food Drug and Cosmetic Act, or "the Act", and its implementing regulations do not exempt veterinarians or pharmacists from the approval requirements in the new animal drug provisions of the Act, 21 U.S.C. Section 360b. In the absence of an approved new animal drug application, the compounding of a new animal drug from any unapproved drug or from bulk drug substances results in an adulterated new animal drug within the meaning of section 21 U.S.C. Section 351(a)(5). The compounding of a new animal drug from an approved human or animal drug also results in an adulterated new animal drug within the meaning of 21 U.S.C. Section 351(a)(5), unless the conditions set forth in 21 CFR 530.13(b) relating to extralable use are met.

FDA is concerned about veterinarians and pharmacists that are engaged in manufacturing and distributing unapproved new animal drugs in a manner that is clearly outside the bounds of traditional pharmacy practice and that violates the Act—such as compounding that is intended to circumvent the drug approval process and provide for the mass marketing of products that have been produced with little or no quality control or manufacturing standards to ensure the purity, potency, and stability of the product.

Pharmacists and veterinarians who engage in activities analogous to manufacturing and distributing drugs for use in animals may be held to the same provisions of the Act as manufacturers.

Question. Finally, the final paragraph of the FDA response states "Accordingly, the regulations that implement AMDUCA provide that extralabel use by compounding applies only to compounding of a product from approved drugs, and that nothing in the regulations is to be construed as permitting compounding from bulk drugs." Is there in the agency's view anything in AMDUCA's regulations or the Act that is to be construed as not permitting compounding from bulk substances?

Answer. As previously noted, under the Federal Food, Drug and Cosmetic Act, in the absence of an approved new animal drug application, the compounding of a new animal drug from a bulk substance results in a new animal drug that is adulterated as a matter of law. This has been FDA's longstanding position, which is supported by two Federal appeals court decisions, *United States* v. *Algon Chemical Inc.,* 879 F.2d 1154 (3d Cir. 1989) and *United States* v. *9/1 Kg. Containers,* 854 F.2d 173 (7th Cir. 1988).

QUESTIONS SUBMITTED BY SENATOR BYRON L. DORGAN

DRUG REIMPORTATION

Question. In Canada and the European Union, all drugs sold in those countries must meet the safety requirements of those countries. Given that, why is the FDA opposed to legalizing the importation of drugs that stayed within their systems? In what areas does the FDA believe that the Canadian or European drug regulatory systems are inferior to its own? Please provide specific examples.

Answer. We have concerns about medicines purchased outside of the United States because they are typically not FDA-approved and they have been manufactured, processed, shipped, and/or held outside the reach of the domestic Federal and State oversight systems intended to ensure that all drugs are safe and effective for their intended uses. The Medicare Prescription Drug, Improvement and Modernization Act of 2003, directed the Secretary of Health and Human Services to conduct a study on the importation of drugs. The Conference Report detailed the information to be included in the study. The information you have requested as to assurances of the safety of imported drugs from Canada and the European Union is information requested as part of the study. We have been actively involved in collecting, analyzing and assessing information, including the safety of such products, the economic implications, the cost of implementation, and expect to provide a comprehensive study to Congress before or by the due date.

Question. How much funding and new personnel do you estimate that the FDA needs in order to implement a safe system of drug importation? [In 2000, FDA estimated that it would need $23 million for the first year of implementation.] What specific additional authorities does the FDA feel it needs to "police imports"?

Answer. FDA made several cost estimates during consideration of the MEDS Act in 2000 and during consideration of other importation legislation. In 2000, FDA estimated that implementation of the MEDS Act would cost $21 million in each of the first 2 years following passage of the legislation, as the agency drafted implementing regulations. Other figures were provided in direct response to particular inquiries. It should be noted that the figures previously calculated were specific to the different legislation and programs reviewed and include limitations on the types of importations. For the MEDS Act, if the program was fully implemented, the cost estimates rose to more than $100 million per year. The information you have requested as to what additional authorities FDA needs to "police imports" is information that is being assessed as part of the Medicare Section 1122 study.

Question. The drug importation provision in the new Medicare law (Section 1121) gives the HHS Secretary the authority to write regulations that "contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs." Is this not enough additional authority to allow FDA to police imports?

Answer. This information will also be assessed as part of the Medicare study, as noted above.

Question. Recently, edible bean shipments were stopped by at the U.S. border from Canada because the beans were contaminated with the chemical "Ronilan," which is banned from use on edible beans in the United States. I come to find out that according to the Food and Drug Administration, less than one-half of 1 percent of the edible beans imported into the United States are inspected. North Dakota is the number one State in dry edible bean production in the country. My farmers have a vested interest in seeing that their industry is protected the importation of contaminated edible beans. What will the FDA do to increase inspections to insure that our edible bean industry is protected?

Answer. Based on sampling conducted and residues found, FDA does not believe that additional testing/sampling beyond what is currently planned is warranted. The common violations involve a pesticide use on a food for which no United States tolerance has been established for that particular food although that pesticide has been registered with EPA and has a tolerance established on other foods. If new information becomes available indicating a compliance problem, whether from FDA sampling or other valid sampling, the FDA will consider increasing the priority for pesticide testing for dried edible beans.

QUESTIONS SUBMITTED BY SENATOR DIANNE FEINSTEIN

LARIUM (MEFLOQUINE)

Question. Mefloquine is an anti-malarial product that is approved and prescribed in the United States but is used by consumers overseas to prevent or treat malaria

infections. There have been many reports in the press about mefloquine's potentially dangerous side effects and FDA issued a press release describing these side effects. With most of the consumers of mefloquine using the product abroad how can we be certain that the reporting of adverse events experienced overseas is occurring sufficient for adequate assessments of risk and benefit during the post-marketing period?

Answer. Adverse event reporting is voluntary for consumers and health care providers. Health care providers or consumers may report to the drug manufacturer (who is required to forward the report to FDA under 21CFR 314.80) or directly to FDA. The reports received are then entered into the AERS database, which is used to evaluate the adverse events associated with a particular drug in the aggregate. This data is used to identify potential drug safety concerns, on which FDA can either take immediate action, or study further in some way. In the case of mefloquine hydrochloride, the response to your next question demonstrates that we are receiving reports of serious adverse events, even though the drug is primarily used while patients are overseas.

Question. How many and what types of adverse events are being reported? Who is submitting the reports, the consumer experiencing the adverse event or the practitioner? Given the serious nature and potential for long term side effects is there a registry or follow-up of consumers of this product, either during use or after finishing use of the product?

Answer. As of April 13, 2004, the FDA's Adverse Event Reporting System (AERS) post marketing database contains 2,786 cases with Lariam® (mefloquine hydrochloride) as a suspect drug. Case reports have been received since Lariam® was approved in 1989 and continue to come to the Agency at a rate of more than 100 per year. For example, AERS has received 139 posts marketing adverse event cases1 associated with Lariam® since April 1, 2003. As with most drugs, many types of adverse events are reported for Lariam®. However, the largest number of reports is for neuropsychiatric events; of the 2,786 Lariam® cases in AERS, 1,821 contain at least one event categorized as neurological and/or psychiatric in nature. Seven of the ten events most frequently reported for Lariam® (see below) are neuropsychiatric in nature:

Dizziness 381 cases;[1] Headache 235; Anxiety 360; Fever 196; Depression 303; Hallucination 179; Insomnia 268; Diarrhea 169; Nausea 238; Abnormal dreams 148.

The Lariam® labeling (package insert) was recently updated to include stronger warnings about neuropsychiatric events. In addition, an official Medication Guide discussing neuropsychiatric and other adverse events, and describing malaria chemoprevention, is required by law to be given to every patient to whom Lariam® is dispensed.

Lariam® reports are being submitted from multiple sources. According to AERS, of the 2,786 reported cases, 512 cases were reported by consumers and 1,540 by health professionals.[2]

Although most Lariam® adverse events occur while the users are traveling, more than 1,500 of the 2,786 Lariam® cases were reported from the United States. This indicates that travelers are notifying their health practitioners, Roche Pharmaceuticals, and/or the FDA directly of adverse events associated with Lariam® upon their return to this country.

There is no registry for follow-up of Lariam® adverse events. It should be noted that post-market reporting is only one component of FDA's adverse event monitoring. Controlled comparative trials give us the most reliable data, and there are many such trials in the published literature. In addition, there are publications describing active surveys, which provide information on very large numbers of patients in a relatively controlled manner.

Question. DOD has begun an investigation into psychiatric adverse events in soldiers and plans a study of mefloquine. DOD has stated that it has not included in its assessments several incidents in soldiers who have taken mefloquine or soldiers who do not demonstrate blood levels of the drug. FDA's News Release of July 9, 2003 states that "Sometimes these psychiatric adverse events may persist even after stopping the medication." What is being done by FDA to investigate the incidents of suicides in soldiers while on or returning from deployment?

Answer. As a general matter, FDA takes numerous steps to improve product and patient safety and reduce medical errors. Suicides in the military are not inves-

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[1] This raw count from AERS probably contains some duplicate cases, as well as cases resulting from literature articles and studies.

[2] The categorization by source includes a large number of cases with null values. In addition, more than one source can be indicated for a given case (for example, both "health professional" and "literature").

tigated by FDA and would fall presumably within the purview of DOD. Frequent discussion between DOD and FDA has occurred related to antimalarial prophylaxis, and DOD has not communicated concerns regarding soldier suicides and the use of Lariam®. Since Lariam® was approved in 1989, AERS has identified 17 cases of suicide worldwide, associated with Lariam® use. These cases are reviewed on an ongoing basis. Many of the cases lack sufficient evidence to conclude that the suicide was related to Lariam®. The relationship between suicide and Lariam® is not conclusive since many of the cases involve previous psychiatric disease or other confounding factors. Only five of the reported cases occurred in U.S. residents, and none of them were soldiers. One, however, was a former Marine who had taken Lariam® while serving in Somalia, more than 6 years before his eventual suicide. Suicides have also been reported with other antimalarial agents including chloroquine and malarone.

Current labeling of Lariam® includes the following warning: Mefloquine may cause psychiatric symptoms in a number of patients, ranging from anxiety, paranoia, and depression to hallucinations and psychotic behavior. On occasions, these symptoms have been reported to continue long after mefloquine has been stopped. Rare cases of suicidal ideation and suicide have been reported though no relationship to drug administration has been confirmed. To minimize the chances of these adverse events, mefloquine should not be taken for prophylaxis in patients with active depression or with a recent history of depression, generalized anxiety disorder, psychosis, or schizophrenia or other major psychiatric disorders. Lariam should be used with caution in patients with a previous history of depression. During prophylactic use, if psychiatric symptoms such as acute anxiety, depression, restlessness or confusion occur, these may be considered prodromal to a more serious event. In these cases, the drug must be discontinued and an alternative medication should be substituted.

A Medication Guide was developed that communicates these issues to the patient.

EMERGENCY CONTRACEPTION

Question. There are reports in the press that decisions about OTC approval of Plan B contraception are being made differently than decisions about other products, made outside the Center, at the Commissioner level or above. Could you explain if this is true, if FDA is politicizing the approval process and why this is the case? Why is the Plan B OTC approval being handled differently from other products?

Answer. The review and decision-making for the Plan B application is not being made differently than other applications. The review is occurring within the FDA's Center for Drug Evaluation and Research. FDA will have signatory authority of the application. The Center commonly involves the Office of the Commissioner in prominent regulatory decisions.

Question. Given that advisory committee members voted unanimously that Plan B Emergency contraception was safe under OTC conditions of use and that studies investigating the OTC instructions, including contraindications, side effects and precautions were well understood by users of the product and that there was low abuse and misuse potential, why has the decision to approve OTC use of Plan B emergency contraception been delayed? When does FDA plan to make a decision on OTC use of Plan B emergency contraception?

Answer. Since the December 2003 joint meeting of two FDA advisory committees, the sponsors of the supplemental new drug application (NDA) submitted additional information to FDA in support of their application to change Plan B from a prescription to an over-the-counter product. This additional information was extensive enough to qualify as a major amendment to the NDA. Under the terms of the PDUFA, major amendments such as this automatically trigger a 90-day extension of the original PDUFA deadline. The PDUFA extension will permit the FDA to complete its review of the application, including additional data on adolescent use that was submitted by Barr and WCC in support of the application. The new PDUFA deadline is May 21st. Such extensions are required so that FDA staff has adequate time to review the additional medical and scientific evidence. FDA's final decision will be based on sound science and in full compliance with the applicable laws and regulations, while taking into consideration the recommendations of these advisory committees.

Question. Plan B, levonorgestrel, has been proven most effective when taken within 24 hours of coitus. Retaining prescription status of this drug impedes the ability of consumers to use the product when it is most effective. If FDA does not anticipate approving Plan B emergency contraception for OTC status, please explain the rationale, when the product has been identified as safe and effective and eligible for

transfer to OTC status under the 1951 Durham-Humphrey Amendment to the Food Drug and Cosmetic Act, that this change in status was not approved?

Answer. FDA is still reviewing the application, so therefore we are unable to answer this question until the review is complete and a decision has been made based on this review.

Question. Some questions were raised by groups against the approval of Plan B as an OTC product, that use of an OTC emergency contraceptive may promote promiscuity in teens. Studies indicated that this was not the case. Is this still an issue for the FDA?

Answer. FDA is still reviewing the application, so therefore we are unable to answer this question until the review is complete and a decision has been made that is based on the safety and efficacy in an OTC setting, which includes comprehension of the label and usage of the product.

QUESTIONS SUBMITTED BY SENATOR RICHARD J. DURBIN

DIETARY SUPPLEMENTS

Question. Do you agree it would be easier for the FDA to remove unsafe dietary supplements from the market if supplement manufacturers were required to submit serious adverse event reports your agency?

Answer. Adverse event reports are one way that FDA may become aware of a potential safety problem.

In evaluating the safety of dietary supplements containing a particular dietary ingredient, we consider evidence from a variety of sources, including: (1) the well-known, scientifically established pharmacology of the ingredient or its constituents; (2) peer-reviewed scientific literature on the effects of the dietary ingredient or its constituents; and (3) adverse events reported to have occurred following consumption of dietary supplements containing the dietary ingredient or its constituents. Therefore, a conclusion that a particular dietary supplement or dietary ingredient should be removed from the market will still rest upon a determination that the available scientific information supports a finding that is adulterated.

Question. How do you respond to the IOM's conclusion in their recent dietary supplement report that "a core issue that constrains the development and utility of a scientifically based framework for evaluating the safety of dietary supplements is the lack of data readily available for evaluation? Without amendment to DSHEA by Congress, the FDA is not empowered to require the submission to the agency of such key information as adverse events."

Answer. In evaluating the safety of dietary supplements, FDA relies on all available information including, the well-known, scientifically established pharmacology of an ingredient or its constituents, peer-reviewed scientific literature on the effects of the dietary ingredient or its constituents, and adverse events reports. Certainly, FDA welcomes the submission of any safety-related information that a firm may have, and such information may facilitate FDA's evaluation of the potential hazards of a dietary ingredient.

Such information often does not resolve the safety questions about an ingredient, however, that is because the major limitation to establishing that a particular dietary ingredient or dietary supplement presents a significant or unreasonable risk is the relatively incomplete scientific information about the pharmacology and effects of many dietary ingredients rather than lack of FDA access to the information a firm may have assembled.

Amending DSHEA to provide FDA access to a firm's safety information would not resolve the basic issue that in many cases there is inadequate information to understand the risk, if any, that a particular dietary ingredient may present to consumers. FDA believes that actions to facilitate the conduce of scientific studies of the composition, pharmacology, and effects of dietary ingredients would be useful in generating the data that the IOM believes is necessary to develop a scientifically based framework for evaluating the safety of dietary supplements.

Question. The definitions of "unreasonable risk" used by FDA in the ephedra rule and the IOM in their report require that only a likelihood of future risk be shown, which would allow the FDA to take supplements that are harmful off the market faster. Do you agree?

Answer. Yes. As FDA stated in the ephedra rule, "unreasonable risk" does not require a showing that a dietary supplement has caused actual harm to specific individuals, only that scientific evidence supports the existence of risk.

Question. I am concerned that the FDA does not have the proper tools, systems, and resources to promptly implement the new "unreasonable risk" standard for die-

tary supplements in future situations. For example, the agency's interpretation of the "unreasonable risk" standard relies in part on an evaluation of the benefits (or lack of benefits) of a particular supplement. What mechanisms, if any, does FDA have in place to evaluate the benefits of dietary supplements?

Answer. In evaluating the benefits of dietary supplements, FDA reviews published studies and other relevant sources of scientific information. Collaboration with academic centers such as the National Center for Natural Products Research (NCNPR), Federal partners such as the National Institutes of Health and the National Center for Toxicological Research, and our consumer and industry stakeholders is important in developing a comprehensive risk-benefit evaluation of dietary supplement products. We believe that efforts to strengthen our relationship with scientific centers that emphasize primarily efficacy research is the best approach to ensure that such information is available, when needed, for safety evaluations under the "unreasonable risk" standard. Further, it is important to recognize that in circumstances in which there is clear and persuasive evidence of a substance's risks but information on its benefits is incomplete or absent there is no barrier to FDA action. Under the risk-benefit analysis that FDA described in the ephedra rulemaking, having efficacy data is not a prerequisite for acting against unsafe dietary supplements; that is, if there is adequate evidence that a product presents a known or reasonably known or reasonably likely risk but there is no data sufficient to show that the product has known or reasonably likely benefits, FDA can take action against the product based on unreasonable risk.

Question. Commissioner McClellan promised enforcement action against bitter orange and usnic acid in the wake of the ephedra decision. Yet, all the agency has done so far is to reiterate its warnings to the public that these supplements pose hazards. Is the lack of efficacy information for these substances hindering prompt FDA regulatory action?

Answer. In a speech at the University of Mississippi in January, Dr. McClellan indicated that FDA might "take a closer look" at the safety of other dietary supplements, specifically naming some ephedra substitutes, such as bitter orange (citrus aurantium) as well as usnic acid. FDA is actively engaged in coordinating research on bitter orange.

At the present time, FDA is examining the available scientific information to determine what safety concerns, if any, may be associated with the use of dietary supplements containing bitter orange and usnic acid. Although FDA cannot predict ahead of time what the findings of this review will be, FDA can assure you that if the evidence establishes that the use of these ingredients in dietary supplements presents an unreasonable risk of injury or illness, FDA will take action to address those risks. In the interim, the Agency feels it is important to keep consumers informed of safety concerns about these substances so that they may make informed decisions about whether or not to use dietary supplements containing them.

Question. The May 2004 edition of Consumer Reports Magazine contains a list of 12 dietary supplement ingredients they recommend consumers stay away from. One of the ingredients is andostenedione, and anabolic steroid, which has already been banned. Will you commit to a full scientific safety review of eleven remaining substances listed by Consumer Reports?

Answer. We continually monitor the marketplace and the scientific literature to identify dietary supplements and dietary ingredients that may present safety concerns. The potential risks presented by different dietary ingredients vary widely. Depending on the specific facts surrounding the characteristics and use of each substance and the risks it may present, FDA will make every attempt to allocate resources to address those that present the most significant public health concerns. As part of on-going dietary supplement marketplace monitoring efforts, FDA will critically examine the list of substances identified by Consumer Reports Magazine and consider the safety risks that they present and what action by FDA may be warranted.

SUBCOMMITTEE RECESS

Senator BURNS. Dr. Crawford, I did not have a question for you. We can get together offline, sir.

Mr. Bost, nice to see all of you here today, and again, thanks for your good work. I think you all are to be commended. That is not to say that we should let our guard down because we know that we still have—any time that you deal in this area of food and food safety and especially for our consumers. They come first. I think

the industry is of a mindset they want to do the right thing but make sure it is the right thing to do, that we just do not give some cosmetic look at it and not address the real problems.

Thank you for coming. These hearings are closed.

[Whereupon, at 2:21 p.m., Thursday, April 1, the subcommittee was recessed, to reconvene subject to the call of the Chair.]